



**REPUBLIC OF ALBANIA
PUBLIC PROCUREMENT AGENCY**

**STANDARD DOCUMENTS FOR
THE OPEN PROCEDURE (ABOVE THE HIGH MONETARY
THRESHOLD) GOODS ¹**

SUBJECT: "Purchase of specific medical materials for the Hemodynamics Service (related to interventions in arrhythmias, IK and valves in the Cardiac Catheterization Laboratory) for QSU "Mother Teresa" for 24 months, divided into lots (7 lots): Lot 1- ICDVR; Lot 2 - Pacemaker VVIR and DDDR; Lot 3 - Pacemaker with antibiotic; Lot 4 - Biventricular pacemaker (CRT-P); Lot 5 - MRI compatible Pacemaker; Lot 6 - Stents for carotis and renal arteries; Lot 7 - Coronary drug-eluting stent with bioabsorbable polymer coating for rapid endothelial (3rd generation);

LIMIT FUND: Framework Agreement Limit Fund / Expected value of contracts that can be concluded during the Framework Agreement (in total for all lots - 7 lots) is: 215,874,330 (two hundred and fifteen million eight hundred and seventy four thousand three hundred and thirty) ALL without VAT and 218,198,330 (two hundred and eighteen million one hundred and ninety three thousand thirty) lek with VAT, divided into lots;

Unit price multiplayer (in total for all lots - 7 lots) is: 10,058,797.83 (ten million fifty-eight thousand seven hundred ninety-seven (points eighty-three .83)) ALL without VAT;

REFERENCE: **REF-70586-09-03-2020**

¹

In the case of non-specific and specific provisions in this set of documents, the contracting authority shall refer to the provisions of the applicable public procurement legislation and rules.

I CONTRACT NOTIFICATION

Section 1. Contracting Authority

1.1 Name and address of the contracting authority

Name 'Mother Teresa' University Hospital Centre.
 Address Dibra Str. No.372, Tirana.
 Tel/Fax Tel. +355 42 362 627 Fax. +355 42 363 644
 E-mail Denis.Veseli@qsut.gov.al
 Web www.qsut.gov.al

1.2 Type of contracting authority:

Central Institution	Independent Institution
<input type="checkbox"/>	<input type="checkbox"/>
Unit of local authorities	Other
<input type="checkbox"/>	✓

1.3 A contract under a special agreement between Albania and another State

Yes ☐ No ✓

Section 2. Object of Contract

2.1 Reference number of procedure / lot REF-70586-09-03-2020

Lot:	No.: Reference :
Lot 1	REF-70593-09-03-2020
Lot 2	REF-70595-09-03-2020
Lot 3	REF-70598-09-03-2020
Lot 4	REF-70600-09-03-2020
Lot 5	REF-70602-09-03-2020
Lot 6	REF-70604-09-03-2020
Lot 7	REF-70606-09-03-2020

2.2 Type of "Public Contract for Goods"

Purchasing	Renting	Leasing	Purchase in installments	A combination of these
✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2.3 Contracts under the Framework Agreement

Yes ✓ No ☐

2.4 Type of Framework Agreement

With one Economic Operator

☐

With few economic operators

☒ *(With a single winning EO for each lot)*

All terms are defined

Yes ☒ No ☐

In the Framework Agreement with 1 Economic Operator, when all conditions are set, the reasons for selecting this type of Framework Agreement

Due to the coverage of the service with the required goods at all times and due to the specifics of the CA (the only Tertiary Health Center in the Republic of Albania), the delivery of this goods by several economic operators for each lot is not favorable and creates difficulties. Contracting authority for timely supply, therefore delivery by one EO for each lot is practically more convenient. Regarding the procurement of this facility, all the main conditions of the framework agreement are defined, such as the article (medical materials), technical specifications, delivery and the expected quantities required. The change of EO in case this agreement would be concluded with several EO for each lot (therefore where not all conditions would be defined) would cause additional costs, uncertainty and confusion for successful EO, which would be accompanied with the increase of delivery deadlines, taking into account that the medical material has an expiration date and the need for timely treatment of CA patients. The connection of MK with a single winning EO for each lot, would be associated with the good organization of the latter for the provision of goods on time, providing a reserve and supply at the time required by the CA. Also, the security for the contracts that are foreseen to be concluded enables the EO to reduce the costs of the offer. Framework agreement with several EOs for each lot where not all conditions are defined is not considered a contract. This means that CA do not have binding mechanisms for EOs declared successful for their participation in mini-competitions and consequently in concluding contracts after their development. Uncertainty and delays can lead to failures in the supply of these materials to the CA in a timely manner, having a direct impact on the patient. In order to guarantee the supplies in the defined timeframes, MK with a single winning EO for each lot would guarantee the security of supplies according to the defined conditions and within the required deadlines, bringing stability in the management of contracts and the needs of the CA.

2.5 Number of economic operators with which the Framework Agreement will be concluded: 1 economic operator for each lot (Please define the maximum number of economic operators with whom the Framework Agreement shall be concluded).

2.6	The terms to be followed in case of reopening of the bidding process and/or potential use of electronic bidding	There will be no reopening of the competition. Contracts will be concluded as per the requirements of the Contracting Authority, with the successful economic operator, which will offer the lowest price (lowest unit price multiplier) required. Contracts will be awarded by "Mother Teresa" University Hospital Center
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2.7 Contracting Authority / Contracting Authorities, which will conclude the framework agreement: University Hospital Center "Mother Teresa".

2.8 Short description of the contract / framework agreement

1. Limit Fund of the Framework Agreement/ Expected value of the contracts that can be concluded during the Framework Agreement (in total for all lots) is **215,874,330 (two hundred and fifteen million eight hundred and seventy four thousand three hundred and thirty) ALL without VAT and 218,198,330 (two hundred and eighteen million one hundred and ninety eight thousand three hundred and thirty) ALL with VAT**, where:

- Lot 1- ICDVR: **34094000 (thirty-four million ninety-four thousand) ALL without VAT and 34198800 (thirty-four million one hundred ninety-eight thousand eight hundred) ALL with VAT**;
- Lot 2 - Pacemaker VVIR and DDDR: **73020499 (seventy-three million twenty thousand four hundred ninety-nine) ALL without VAT and 73424599 (seventy-three million four hundred twenty-four thousand five hundred and ninety-nine) ALL with VAT**;
- Lot 3 - Pacemaker with antibiotic, **7857000 (seven million eight hundred and fifty-seven thousand) ALL without VAT and 7857000 (seven million eight hundred and fifty-seven thousand) ALL with VAT**;
- Lot 4 - Biventricular pacemaker (CRT-P): **21306000 (twenty-one million three hundred and six thousand) ALL without VAT and 21717200 (twenty-one million seven hundred seventeen thousand two hundred) ALL with VAT**;
- Lot 5 - Pacemaker MRI compatible: **37078000 (thirty-seven million seventy-eight thousand) ALL without VAT and 37299600 (thirty-seven million two hundred ninety-nine thousand six hundred) ALL with VAT**;
- Lot 6 - Stents for carotis and renal arteries: **11852167 (eleven million eight hundred and fifty-two thousand one hundred and sixty-seven) ALL without VAT and 13034467 (thirteen million thirty-four thousand four hundred sixty-seven) ALL with VAT**;
- Lot 7 - Coronary drug-eluting stent with bioabsorbable polymer coating for rapid endothelial (*3rd generation*): **30666664 (thirty million six hundred and sixty-six thousand six hundred sixty-four) ALL without VAT and 30666664 (thirty million six hundred sixty-six thousand six hundred sixty-four) ALL with VAT**;

2. In case the procurement object consists of several items, **the unit price multiplier (in total for all lots) is: 10,058,797.83 (ten million fifty-eight thousand seven hundred ninety-seven .83 (points eighty-three) ALL without VAT**, where:

- Lot 1- ICDVR: **797200 ALL without VAT**;
- Lot 2 - Pacemaker VVIR and DDDR: **210247 ALL without VAT**;
- Lot 3 - Pacemaker with antibiotic, **940000 ALL without VAT**;
- Lot 4 - Biventricular pacemaker (CRT-P): **1467300 ALL without VAT**;

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- Lot 5 - Pacemaker MRI compatible: **319400 ALL without VAT;**
- Lot 6 - Stents for carotis and renal arteries: **1341499.93 ALL without VAT;**
- Lot 7 - Coronary drug-eluting stent with bioabsorbable polymer coating for rapid endothelial (*3rd generation*): **4983332.9 ALL without VAT;**

3. Source of Financing: **State budget**

4. Object of the contract / framework agreement: **Purchase of specific medical materials for the Hemodynamics Service (related to interventions in arrhythmias, IK and valves in the Cardiac Catheterization Laboratory) for QSU "Mother Teresa" for 24 months, divided into lots (7 lots):**

Lot 1	ICDVR
Lot 2	Pacemaker VVIR and DDDR
Lot 3	Pacemaker with antibiotic
Lot 4	Biventricular pacemaker (CRT-P)
Lot 5	Pacemaker MRI compatible
Lot 6	Stents for carotis and renal arteries
Lot 7	Coronary drug-eluting stent with bioabsorbable polymer coating for rapid endothelial (<i>3rd generation</i>)

2.9 Duration of the contract or time-limit for the execution of the contract:

Duration in month's 24 or days ☐☐☐

Or

Starting from ☐☐☐☐☐☐ ending in ☐☐☐☐☐☐

2.9.1. Duration of the Framework Agreement: **24 months after the signature of the Framework Agreement.**

Duration in months: 24 or days <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> (after the signature of the Framework Agreement (no more than 4 years) <i>Or starting from</i> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> (dd/mm/yyyy) Completed on <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> (dd/mm/yyyy)
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2.10 Place of delivery of the contract object / framework agreement:

At the University Hospital Center "Mother Teresa", in Tirana, Albania

2.11 Division into LOTS:

Yes



No



If yes,

2.12 Brief description of lots

(Objective and limit fund of Lots)

Purchase of specific medical materials for the Hemodynamics Service (related to interventions in arrhythmias, IK and valves in the Cardiac Catheterization Laboratory) for QSU "Mother Teresa" for 24 months, divided into lots (7 lots), Framework agreement with several economic operators (With a single winning EO for each lot), where all conditions are defined ” – duration of the framework agreement two years (24 months) from signing. Limit Fund / Expected value of the contracts that can be concluded during the Framework Agreement (in total for all lots – 7 lots): 215,874,330 (two hundred and fifteen million eight hundred and seventy four thousand three hundred and thirty) ALL without VAT and 218,198,330 (two hundred and eighteen million one hundred and ninety eight thousand three hundred and thirty) ALL with VAT, divided into lots as below:

- **Lot 1- ICDVR: 34094000 (thirty-four million ninety-four thousand) ALL without VAT and 34198800 (thirty-four million one hundred ninety-eight thousand eight hundred) ALL with VAT;**

Unit price multiplier 797200 ALL without VAT;

- **Lot 2 - Pacemaker VVIR and DDDR: 73020499 (seventy-three million twenty thousand four hundred ninety-nine) ALL without VAT and 73424599 (seventy-three million four hundred twenty-four thousand five hundred and ninety-nine) ALL with VAT;**

Unit price multiplier 210247 ALL without VAT;

- **Lot 3 - Pacemaker with antibiotic, 7857000 (seven million eight hundred and fifty-seven thousand) ALL without VAT and 7857000 (seven million eight hundred and fifty-seven thousand) ALL with VAT;**

Unit price multiplier 940000 ALL without VAT

- **Lot 4 - Biventricular pacemaker (CRT-P): 21306000 (twenty-one million three hundred and six thousand) ALL without VAT and 21717200 (twenty-one million seven hundred seventeen thousand two hundred) ALL with VAT;**

Unit price multiplier 1467300 ALL without VAT;

- **Lot 5 - Pacemaker MRI compatible: 37078000 (thirty-seven million seventy-eight thousand) ALL without VAT and 37299600 (thirty-seven million two hundred ninety-nine thousand six hundred) ALL with VAT;**

Unit price multiplier 319400 ALL without VAT;

- **Lot 6 - Stents for carotis and renal arteries: 11852167 (eleven million eight hundred and fifty-two thousand one hundred and sixty-seven) ALL without VAT and 13034467 (thirteen million thirty-four thousand four hundred sixty-seven) ALL with VAT;**

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Unit price multiplier 1341499.93 ALL without VAT;

- Lot 7 - Coronary drug-eluting stent with bioabsorbable polymer coating for rapid endothelial (*3rd generation*): **30666664 (thirty million six hundred and sixty-six thousand six hundred sixty-four) ALL without VAT and 30666664 (thirty million six hundred sixty-six thousand six hundred sixty-four) ALL with VAT;**

Unit price multiplier 4983332.9 ALL without VAT;

A Bidder may apply for [one lot], [several lots], [all lots]. A separate offer for each lot must be submitted.

2.13 Options:

Number of possible renewals (*if any*): **NO**

Or: from ☐ ☐ to ☐ ☐

2.14 Variants will be accepted:

Yes ☐ No ☒

2.14.1 Subcontracting will be accepted:

Yes ☐ No ☒

If subcontracting is allowed, specify the percentage allowed for subcontracting: ____

The contracting authority will make direct payments to the subcontractor:

Yes ☐ No ☐

Other notes

Note ¹: For comparison purpose, the evaluation of the submitted bids will be done on the basis of the total value offered for each lot (*unit price bid X expected quantity*). Framework Agreement based contracts will be awarded on the basis of the unit price of the successful bid announced.

Caution*: The total unit price per lot shall not exceed the unit price multiplier published in these TDs. The expected value of lot contracts should not exceed the limit fund of FA per lot. Otherwise the offer will be rejected.

Note ²: - The Framework Agreement will signed according the Limit Fund value of each lot specified in these STDs. - Upon exhaustion of the Limit Fund or FA deadline, the Framework Agreement for each lot shall expire.

2.15. During the procurement process in the field of Information and Communication Technology (ICT) the standards prepared by the National Agency of Information Society are used:

Yes ☐ No ☐

2.16. During the procurement process in the field of Information and Communication Technology (ICT), in the case the standards are not applicable, a prior approval is received from the National Agency of Information Society:

Yes ☐ No ☐

Section 3 Legal, Economic, Financial and Technical Information

3.1 Qualification Criteria according to Appendix 9.

3.2 Bid Insurance²: 2% of the Limit Fund (The Economic Operator submits the Bid Security Form, according to Appendix 4) the required bid security value for all Lots in Total (7 lots) is **4317486.6 (four million three hundred seventeen thousand four hundred eighty-six ,6) ALL.**

In cases of bid submission for separate Lots, the bid insurance value for each of the Lots is as below:

- Lot 1- ICDVR: **681880** (six hundred eighty-one thousand eight hundred eighty) **ALL;**
- Lot 2 - Pacemaker VVIR and DDDR: **1460409.98** (one million four hundred sixty thousand four hundred nine .98 (. ninety-eight) **ALL;**
- Lot 3 - Pacemaker with antibiotic: **157140** (one hundred and fifty-seven thousand one hundred and forty) **ALL;**
- Lot 4 - Biventricular pacemaker: (CRT-P): **426120** (four hundred twenty-six thousand one hundred twenty) **ALL;**
- Lot 5 - Pacemaker MRI compatible: **741560** (seven hundred forty-one thousand five hundred sixty) **ALL;**
- Lot 6 - Stents for carotis and renal arteries: **237043.34** (two hundred thirty-seven thousand forty-three .34 (. thirty-four) **ALL;**

² Bid insurance (bond) is not required in procurement procedures of lower value than the high monetary threshold

- Lot 7 - Coronary drug-eluting stent with bioabsorbable polymer coating for rapid endothelial (3rd generation): **613333.28** (six hundred thirteen thousand three hundred thirty-three .28 (twenty-eight) **ALL**;

Section 4 Procedure

4.1 Type of procedure: Open (Over the High Monetary Boundary) - Electronic Procurement (Framework Agreement) 24 months from signing of the FA).

Re - announced procurement procedure

Yes ☐ No ☒

If it's a re-announced procedure, please complete the identification data of the canceled procedure:

a) Reference number in the electronic procurement system of the canceled procurement procedure _____

b) Procurement object of the canceled procurement procedure _____

c) Limit Fund of canceled procurement procedure _____

4.2 Selection Criteria for the Winner:

A) Lowest price ✓

Note 1: For comparison purpose, the evaluation of the submitted bids will be done on the basis of the total value offered for each lot (*unit price bid X expected quantity*). Framework Agreement based contracts will be awarded on the basis of the unit price of the successful bid announced.

Caution*:

The total unit price per lot shall not exceed the unit price multiplier published in these TDs. The expected value of lot contracts should not exceed the limit fund of FA per lot. Otherwise the offer will be rejected.

Note 2: - The Framework Agreement will signed according the Limit Fund value of each lot specified in these STDs. - Upon exhaustion of the Limit Fund or FA deadline, the Framework Agreement for each lot shall expire.

In case of procurement procedures for supply of fuel, gas, gasoline and heating fuel, the **lowest price** is based on:

- i) the stock exchange price, according to Reuters, provided under the CIF-Albania condition, which is published in the last Bulletin of Public Notices, prior to the date of submission and opening of bids;
- ii) fiscal elements, including the excise tax, carbon tax and any other tax under the legislation in force;
- iii) The lowest profit margin, expressed as a percentage.

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The absolute value of the profit margin will not change during the execution of the contract in case of price fluctuations.

Or

B) the most economically advantageous bid ☐

As per importance: Price ☐☐ **Points**

Etc. ☐☐ **Points**

The Contracting Authority shall specify the points for each established evaluation criteria.

4.3 Deadline for submission of bids or requests for participation:

Date: **21/10/2020** (dd/mm/yyyy) Time: **10:00**

Vendi: www.app.gov.al

When the bid is required to be submitted electronically, the bidders shall submit it electronically to the APP official website, www.app.gov.al

4.4 Deadline for the opening of bids or requests for participation:

Date: **21/10/2020** (dd/mm/yyyy) Time: **10:00**

Place: www.app.gov.al

Information on bids submitted electronically shall be transmitted to all those Economic Operators who have submitted bids upon their request.

4.5 Period of bid validity: 180 (one hundred eighteen) Days;

4.6 Language(s) in which bids or requests may be drawn up: *Albanian or English*

Albanian ☒ English ☒

Other _____

Section 5 Additional information

5.1 Payable documents (applicable only to procedures not conducted by electronic means):

Yes ☐ No ☒

If yes

Currency _____ Price _____

This price covers the current costs of copying and distribution of TD to the Economic Operators. The interested Economic Operators have the right to check TD before their purchase.

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5.2 Additional Information (place, office, method for the withdrawal of the bid documents)

Date of delivery of this notice: **04/09/2020**

Contract Notification to be completed by the Contracting Authority, which is to be published in the Public Notifications Bulletin

1.1 Name and address of the contracting authority

Name 'Mother Teresa' University Hospital Centre.
 Address Dibra Str. No.372, Tirana.
 Tel/Fax Tel. +355 42 362 627 Fax. +355 42 363 644
 E-mail Denis.Veseli@qsut.gov.al
 Web www.qsut.gov.al

2. Type of procurement procedure: open, over the high monetary threshold - procurement by electronic means – goods

3. Reference number of procedure / lots: REF-70586-09-03-2020

Lot:	No.: Reference :
Lot 1	REF-70593-09-03-2020
Lot 2	REF-70595-09-03-2020
Lot 3	REF-70598-09-03-2020
Lot 4	REF-70600-09-03-2020
Lot 5	REF-70602-09-03-2020
Lot 6	REF-70604-09-03-2020
Lot 7	REF-70606-09-03-2020

4. Object of the contract / framework agreement: Purchase of specific medical materials for the Hemodynamics Service (related to interventions in arrhythmias, IK and valves in the Cardiac Catheterization Laboratory) for QSU "Mother Teresa" for 24 months, divided into lots (7 lots):

Lot 1	ICDVR
Lot 2	Pacemaker VVIR and DDDR
Lot 3	Pacemaker with antibiotic
Lot 4	Biventricular pacemaker (CRT-P)
Lot 5	Pacemaker MRI compatible
Lot 6	Stents for carotis and renal arteries
Lot 7	Coronary drug-eluting stent with bioabsorbable polymer coating for rapid endothelial (<i>3rd generation</i>)

5. Limit Fund of the Framework Agreement/ Expected value of the contracts that can be concluded during the Framework Agreement (in total for all lots) is **215,874,330 (two hundred and fifteen million eight hundred and seventy four thousand three hundred and thirty) ALL without VAT** and **218,198,330 (two hundred and eighteen million one hundred and ninety eight thousand three hundred and thirty) ALL with VAT**, where:

- Lot 1- ICDVR: **34094000 (thirty-four million ninety-four thousand) ALL without VAT** and **34198800 (thirty-four million one hundred ninety-eight thousand eight hundred) ALL with VAT**;
- Lot 2 - Pacemaker VVIR and DDDR: **73020499 (seventy-three million twenty thousand four hundred ninety-nine) ALL without VAT** and **73424599 (seventy-three million four hundred twenty-four thousand five hundred and ninety-nine) ALL with VAT**;

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- Lot 3 - Pacemaker with antibiotic, **7857000** (seven million eight hundred and fifty-seven thousand) **ALL without VAT** and **7857000** (seven million eight hundred and fifty-seven thousand) **ALL with VAT**;
- Lot 4 - Biventricular pacemaker (CRT-P): **21306000** (twenty-one million three hundred and six thousand) **ALL without VAT** and **21717200** (twenty-one million seven hundred seventeen thousand two hundred) **ALL with VAT**;
- Lot 5 - Pacemaker MRI compatible: **37078000** (thirty-seven million seventy-eight thousand) **ALL without VAT** and **37299600** (thirty-seven million two hundred ninety-nine thousand six hundred) **ALL with VAT**;
- Lot 6 - Stents for carotis and renal arteries: **11852167** (eleven million eight hundred and fifty-two thousand one hundred and sixty-seven) **ALL without VAT** and **13034467** (thirteen million thirty-four thousand four hundred sixty-seven) **ALL with VAT**;
- Lot 7 - Coronary drug-eluting stent with bioabsorbable polymer coating for rapid endothelial (*3rd generation*): **30666664** (thirty million six hundred and sixty-six thousand six hundred sixty-four) **ALL without VAT** and **30666664** (thirty million six hundred sixty-six thousand six hundred sixty-four) **ALL with VAT**;

Unit price multiplier (in total for all lots) is: 10058797.83 (ten million fifty-eight thousand seven hundred ninety-seven .83 (*points eighty-three*) **ALL without VAT**, divided into lots:

- Lot 1- ICDVR: **797200** **ALL without VAT**;
- Lot 2 - Pacemaker VVIR and DDDR: **210247** **ALL without VAT**;
- Lot 3 - Pacemaker with antibiotic, **940000** **ALL without VAT**;
- Lot 4 - Biventricular pacemaker (CRT-P): **1467300** **ALL without VAT**;
- Lot 5 - Pacemaker MRI compatible: **319400** **ALL without VAT**;
- Lot 6 - Stents for carotis and renal arteries: **1341499.93** **ALL without VAT**;
- Lot 7 - Coronary drug-eluting stent with bioabsorbable polymer coating for rapid endothelial (*3rd generation*): **4983332.9** **ALL without VAT**;

6. Duration of the contract or deadline for its execution: The contracts can be signed by the Contracting Authority within a 24-month period from the date of the signing of the framework agreement by the parties, for each of the LOTS.

7. Deadline for the submission of bids or requests for participation:

Date: **21/10/2020** (*dd/mm/yyyy*) Time: **10:00**

Place: www.app.gov.al

8. Deadline for the opening of bids or requests for participation:

Date: **21/10/2020** (*dd/mm/yyyy*) Time: **10:00**

Place: www.app.gov.al

II. INSTRUCTIONS FOR ECONOMIC OPERATORS

Section 1. Drafting of the bid

- 1.1 Economic operators are obliged to prepare bids in accordance with the requirements established in these TD. Bids that are not prepared in accordance with these TD shall be rejected as non - compliant.
- 1.2 The Economic operator/supplier shall bear all costs associated with the preparation and submission of his bid. The Contracting Authority is not responsible or liable for those costs.
- 1.3 Regarding the procurement procedures developed in a written form, the original of the bid shall be typed or written in indelible ink. All bid sheets shall be firmly bounded together and paged. All bid sheets except for unchangeable printed literature shall be initialed or signed by Authorized Person(s). Any changes to the bid shall be legible and signed by Authorized Persons.
- 1.4 In case of the bids are submitted by a merger of economic operators (consortium), the bid shall be accompanied by a power of attorney/written authorization for the Authorized Persons, who will represent the consortium during the procurement procedure.
- 1.5 The Economic Operator shall be responsible for all documentation submitted as part of the Bid. In case of verification of the content of the submitted documentation, or of self-declarations, when their content does not prove to be true, the economic operator is in the conditions provided for in Article 13, paragraph 3, letter (a) of the Law on Public Procurement (PPL).
- 1.6 **The Bid shall include the following documents:**
 - a) Bid Form, completed as per Appendix 1 of TD or Appendix 2 of TD (in the case of procurement procedures for the supply of fuel, gasoline, benzene and heating fuel).
 - b) Documents related to the procurement object (sketches, catalogs, samples, etc.)
_____,
_____,
_____.
 - c) Statement of Independent Bid Submission under Appendix 2/1.
 - ç) The documents and certificates required in Appendix 8.
 - d) (Option) Alternative Technical Bid (if applicable)

An Economic Operator must submit only one bid.

Upon completion of the Appendix "Statement on the Enforcement of the Legal Provisions in Labor Relations", the economic operator acknowledges that it has employment contracts with each employee and that it respects the rights of employees, in accordance with the provisions of the

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Labor Code (including the rights of employees), those of pregnant woman, new mothers and / or mothers that are nursing a newborn, as provided for in Articles 104, 105, 105 / a, 106, 108 and 115, and labor legislation as a whole.

- 1.7 Process confidentiality according to article 25 of the PPL.
- 1.8 Regarding to procurement procedures, which are developed in a written form, the economic operators shall submit only the original bid sealed in one non - transparent envelope, stamped and signed with the name and address of the Bidder and marked: “Bid for Supply of Goods; Notice No _.

“DO NOT OPEN, EXCEPT IN PRESENCE OF THE BID EVALUATION COMMISSION, NOT BEFORE -----dd/mm/yy, at ----- hrs”.

If the submission of the offer is required to be done electronically, the economic operator shall submit the bid electronically in the official website of PPA, www.app.gov.al.

- 1.9 Regarding to procurement procedures which are developed in a written form, the bidders may modify or withdraw their bids provided modification or withdrawal is done before the expiry of the final time limit for bids’ submission. Both modifications and withdrawals shall be communicated to the Contracting Authority in writing, before the final deadline for bids’ submission. The envelope containing statement of Bidders shall be marked: **“MODIFICATION OF BID” or “WITHDRAWAL OF BID” accordingly.**

In case of electronic procurement, the bidder may modify his offer any time prior to the final deadline for the opening (submission) of bids without having to communicate with the Contracting Authority, after the transactions are carried out in his account in the official website of PPA, www.app.gov.al.

Section 2 Economic Offer (Bid) Calculation

- 2.1 An economic operator shall complete the Bid Form attached to this TD, indicating the goods to be delivered, their quantities and price.
- 2.2 All prices shall be quoted in Albanian Currency (ALL), including all applicable taxes, but not VAT. If the prices are quoted in a foreign currency, they will be converted into Albanian ALL (ALL) at the exchange rate fixed by the Central Bank of Albania on the day the contract notification is published and maintained at that exchange rate until the expiry of the bid validity period.
- 2.3 The Bidder must indicate in the Bid Form, the total bid prices of all Goods excl. the VAT. VAT value, when applied, is added to the price given and represents the total value of the bid.
- 2.4. In the case of a framework agreement where all conditions are NOT specified, the prices for contracts based on the framework agreement are not fixed; they are subject to change after a Mini - competition between economic operators, parties to the framework agreement.
- 2.5 The Bid Insurance (Bond), when required, shall be submitted together with the bid before the expiry of the deadline for the submission of bids. Non – compliance with the bid insurance requirements shall result in the rejection of bids.

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2.6 The Bid Insurance may be submitted in one of the following forms:

- a) Bank guarantee
- b) Insurance guarantee

The Bid Insurance Form shall be signed by the issuer (Bank, Insurance Company, etc) and submitted together with the bid, before the opening of bids; otherwise the bid shall be rejected.

The above documents must be valid throughout the validity period of the bid. In the case when the security of the bid is in the form of a bank guarantee, the Contracting Authority shall return the relevant insurance to the bidders within 15 days of the signing of the contract.

2.7 Bid validity period

Bids shall be valid from the moment of expiry of the deadline for the submission of bids. As long as the bid validity period has not expired, the Contracting Authority may request the Bidder in writing to extend the validity period until a specified date. Bidder may reject such a request without losing the right to reimbursement of the Bid Security. Bidders, who agree to extend the bid validity period and notify the Contracting Authority accordingly in writing, shall extend the validity period of the bid and provide an extended bid security. The bid shall not be modified. If the Bidder fails to respond to the request made by the Contracting Authority as regards extension of the bid validity period, or does not extend the validity period, or fails to provide an extended bid security, the Bidder shall be deemed to have rejected the request of the Contracting Authority. In such case, the Contracting Authority will reject the bid.

2.8 Illegal actions according to Article 26 of PPL

Section 3. Evaluation of Bids

3.1 Selection criteria

(Option 1) The lowest price of the qualified bid.

The contract shall be awarded to the Bidder who has offered the lowest bid price.

In the case of procurement procedures for the supply of fuel, gas, benzene and heating fuel, the **lowest price** is based on:

- i) The stock exchange price, according to Reuters, provided under the CIF-Albania condition, which is published in the last Bulletin of Public Notices, prior to the date of submission and opening of bids;
- ii) Fiscal elements, including excise tax, carbon tax and any other tax under the legislation in force;
- iii) The lowest profit margin, expressed as a percentage.

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The absolute value of the profit margin will not change during the execution of the contract in case of price fluctuations.

(Option 2) The most economically advantageous bid.

Regarding to evaluation criteria, the specific weight of each criterion should be specified, namely, the number of points for each criterion and the way how points for consecutive bidders shall be calculated.

All the established criteria for evaluation of bids shall be objective and be expressed in figures. In each case, when there is more than one criterion, the weight of price criterion shall not be less than 50 points. The maximum points to be acquired for a bid shall be 100.

The formula by which bidders points are calculated, in each case shall be:

$$Po = Pk1 + Pk2 + Pk3 + \dots$$

Where:

Po - are total points of the evaluated bid

Pk1/Pk2/Pk3/... - are the points for each evaluated criterion

The points for each criterion are calculated according to the formula:

$$Pk1 = V_{min\ k1} \times P_{maxk1} / O_{k1}$$

Pk1 _____	Points of criterion to be evaluated
Vmin k1	lowest value of the criterion to be evaluated
Pmaxk1	Maximum points given to the evaluated criterion
Ok1	Bid's indicator for the evaluated criterion

Explanation: Only one of the options will be selected as evaluation criteria. Filling both options makes the procedure null and void.

3.2 Correction of errors and omissions

3.2.1 The Contracting Authority shall correct any error in a bid that is of a purely arithmetical nature, if such an error is discovered during the examination of bids. The Contracting Authority shall promptly provide the concerned Bidder with a written notification of any such correction and may proceed to amend the error, provided that the Bidder has approved the communication. If the Bidder refuses to endorse the proposed correction, the bid shall be rejected without the bid security's forfeit, if any.

3.2.2 Errors in price calculation shall be corrected by the Contracting Authority using the

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following assumptions:

- where there is a discrepancy between amounts expressed in figures and in words, the amount in words shall prevail, unless the amount expressed in words is related to an arithmetic error,
- if there is a discrepancy between the unit price and the total amount that is obtained from the multiplication of the unit price and quantity, the unit price shall prevail and the total value shall be corrected,
- if there is an error in the total amount, corresponding to the addition or subtraction of subtotals, the subtotal shall prevail and the total shall be accordingly corrected. Amounts corrected in this way shall be binding on the bidder. If the bidder does not accept them, its bid shall be rejected. *The bids with arithmetic errors shall be refused when the absolute amounts of all corrections are higher or lower than $\pm 2\%$ of the value of offered economic bid.*

3.3 Abnormally low Offers

3.3.1 If the submitted offer results abnormally low in relation to the goods offered, the Contracting Authority requires the Bidder to justify the price offered. If the Bidder fails to provide an excuse to convince the Contracting Authority, the latter has the right to reject the offer.

3.3.2 Offers will be considered abnormally low, as defined in chapter V, paragraph 4 (g) of the PPR.

In case, where are worth two, or fewer bids, in accordance with Article 56 of the LPP/PPL, a bid is estimated as abnormally low, when it is lower than 40 percent of the calculated fund limit.

In case, where are worth three, or more bids, in accordance with Article 56 of the PPL, a bid is estimated as abnormally low, if its value is less than 80 percent of the average of the valid bids.

If one, or more bids are evaluated as abnormally low, the evaluation committee shall seek clarification from the bidders, before taking decision, in respect thereof, in accordance with Article 56 of the PPL."

The formula to be applied, to consider an abnormally low bid, in the case, when there are three, or more valid bids is, as follows:

O - Offer

MO – Average of valid Bids

n - Number of valid Bids

PA - Possible Rebate

$$M_0 = O_1 + O_2 + O_3 + \dots O_n / n$$

PA = 85 % Mo

Evaluated bid value <... PA consequently the bid is Abnormally Low

In the case when the evaluation criterion is selected the most economically favorable bid, it will be verified if the bids are abnormally low only if the bid classified with the highest points has the economic bid with the lowest value.

3.4. Administrative appeal available to Economic Operators under section 63 of the PPL.

Section 4. Contract Signing

4.1 Notification of Winner

The Contracting Authority shall inform the Bidder whose offer was selected as the best one, by sending the contract award notification, as provided in Appendix 14. A copy of this notification shall be published in the Public Notifications Bulletin, as required by article 58 of the PPL.

4.2 Contract Insurance (Bid Bond)

4.2.1 The Contracting Authority shall require a insurance for the contract performance. The amount of the insurance coverage for the contract performance shall be 10 % of the contract value. The contract insurance form, as provided in Appendix 19 of the TD shall be signed and submitted before signing the contract.

4.2.2 The insurance for the contract performance may be submitted in one or more of the following forms:

- i. bank guarantee
- ii. insurance guarantee

This form is not used by contracting authorities in the case of procurement of sectional contracts.

4.3 Notification of the signed contract

Pursuant to the PP Rules, after signing the contract, the Contracting Authority shall send a notification to the PPA for Publication in the Public Notifications Bulletin.

Note: The contracting authorities shall not make any modifications in the tender documents, from clause 1 to 4.

III. APPENDIXES

The following Appendixes are an integral part of the TD:

Appendix 1:	Bid Form
Appendix 2:	Economic Bid Form, in the case of procurement procedures for the supply of fuels, gasoil, benzene and heating fuel
Appendix 2/1:	Statement of Independent Bid Submission
Appendix 3:	Invitation to Bid in the case of the Framework Agreement
Appendix 4:	Bid Insurance Form
Appendix 5:	Confidential Information Form
Appendix 6:	Statement on the fulfillment of technical specifications from the economic operator
Appendix 7:	Statement on Conflict of Interest
Appendix 8:	Statement on the fulfillment of general criteria
Appendix 8/1:	Statement on the Enforcement of the Legal Provisions in Labor Relations
Appendix 9:	General Admissions / Qualification Criteria
Appendix 10:	Technical Specifications
Appendix 11:	Planning of framework agreement contracts
Appendix 12:	Quantity of goods, and delivery conditions
Appendix 13:	Notification of Disqualification Form
Appendix 14:	Award of Contract Notification Form
Appendix 15:	Form of Notification of the Successful Economic Operators in the Framework Agreement
Appendix 16:	General Conditions of the Contract
Appendix 17:	Special Conditions of the Contract
Appendix 18:	Form of Signed Contract Notification
Appendix 18/1:	Form of Signed Contract Notification for publication in the Public Notices Bulletin
Appendix 19:	Contract Insurance Form
Appendix 20:	Complaints to the Contracting Authority Form
Appendix 21:	Draft of the Framework Agreement where all of the terms are defined
Appendix 22:	Draft of the Framework Agreement where not all of the terms are defined
Appendix 23:	Cancellation Notice Form

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Appendix 1

[Appendix to be completed by the economic operator]

BID STATEMENT FORM

Bidder's name _____

To: [Name and address of the contracting authority]

* * *

The procurement procedure: [type of procedure]

Short description of the contract: [subject]

Publication (if applicable): Public Notifications Bulletin [Date] [Number] /No/Reference on the PPA page

* * *

With reference to the above-mentioned procedure we, the undersigned, declare that:

1. The total price of our bid is [currency and amount of the bid]; VAT excluded;
2. The total price of our bid is [currency and amount of the bid]; VAT included

1	2	3	4	5	6
No.	Description of the goods	Quantity	Price per Unit	Total Price	Deadline
Net Price					
VAT (%)					
TOTAL PRICE					

Bidder's Signature _____

Seal _____

Note: Prices shall be expressed in the currency ____ **ALL** _ (required in tender documents

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Appendix 2

[Appendix to be completed by the economic operator in the case of procurement procedures for the supply of fuel, gas, benzene and heating fuel]

ECONOMIC BID FORM

Name of Bidder _____

To: [Name and address of the contracting authority]

* * *

Procurement procedure: [type of procedure]

Short description of the contract: [object]

Publication (if applicable): Public Notices Bulletin [Date] [Number]

* * *

Referring to the aforementioned procedure, we, the undersigned, declare that:

1. 1. Our profit margin expressed in percentage is as follows:

1	2	3	5
No	Description of goods	Margin of profit expressed in percentage	Delivery deadline

Bidder's signature _____

Seal _____

Appendix 2/1

[Appendix to be completed by the Economic Operator]

STATEMENT

Regarding the Independent Submission of the Bid

Of the economic operator participating in the public procurement procedure to be held on: _____; by the Contracting Authority: _____; object: _____; with limit fund: _____.

I, the undersigned, _____, as the representative of the economic operator _____, pursuant to Article 1 of Law no. 9643, dated 20.11.2006 "On Public Procurement", as amended and in support of Law No. 9121/2003 "On Protection of Competition", I make this statement and warrant that the following statements are true and complete in all respects :

I certify, in the interest of: _____ that:
(Name of the economic operator)

1. I have read and understood the contents of this Statement;
2. I understand that the Bid submitted will not be Qualified and / or Excluded from Participation in Public Procurement, if this Declaration is found not to be complete and / or accurate in any respect;
3. I am authorized by the Bidder to confirm this Statement and submit a bid on the Bidder's interest;
4. Any person whose signature appears in the Bid Documentation is authorized by the Bidder to prepare and sign the Bid in the Bidder's interest;
5. For the purpose of this Statement and Bid, I understand that the word "competitors" means any other economic operator, other than the Bidder, whether or not presented as a combination of economic operators, that:
 - a) Submit a bid in response to the Contract Notice and / or Invitation to Bid made by the Contracting Authority;
 - b) Is a potential Bidder who, based on his qualifications, skills or experience, may submit an Offer in response to the Contract Notice and / or Invitation to Bid?

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6. The Bidder states that: (select one of the following alternatives):

a) The Bidder has prepared his Bid independently, without consulting, communicating and making deals or agreeing with any other competitors;

☐

b) The Bidder has consulted, communicated, entered into an agreement with one or more competitors in connection with this procurement procedure. The Bidder states that the attached documents, in the details of this Bid, include the names of the competitors, the nature and causes of the consultation, communication, agreement or engagement (the case of the merger or subcontracting).

☐

7. in particular, without prejudice to paragraphs 6. a) and 6. b) Above, there has been no consultation, communication, contract or agreement with any competitor regarding:

a) Prices;

b) The methods, factors or formulas used to calculate the price;

c) Intention or decision to submit an offer or not; or

d) The filing of a Bid that does not meet the specification of the Bid Request.

8. In addition, there have been no consultations, communications, agreements or contracts with any competitors regarding the particular quality, quantity, specifications or deliveries of the products or services related to the procurement in question, except as stated in paragraph 6.b). Above.

9. The Bid terms have not been made known to or will not be intentionally made known by the Bidder to other competitors, in any way, prior to the date and time of the official opening of bids, the award of the contract and the conclusion of the contract. , unless required by law or specifically stated under paragraph 6.b).

(Name and Signature of the Authorized Representative of the Bidder)

(Title by job position)

(Date)

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Appendix 3

[Appendix to be completed by the contracting authority in the framework agreement at the reopening of the mini - competition process]

INVITATION TO BID

(Insert the name of the Contracting Authority) invites to submit bids in the procedure for the supply of the following goods:

.....
.....
.....

(Give an exact description of the object of the contract and the quantity as defined in the Bidding Documents (TD)

Place of delivery

(Give a brief description)

Goods must be submitted by the date _____

Offers must be submitted

.....

[give the *correct address*]

Before

.....

[Determine the date and time]

Criteria for determining the winning bid _____

The form of communication:

Writing form ☐

electronic form (e-mail, fax, etc.) ☐

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Appendix 4.

[Letterhead of the Bank / Insurance Company]

[Appendix to be submitted by the economic operator when required by the contracting authority]

BID INSURANCE FORM

[Date]

To: *[Name and address of the contracting authority]*

On behalf of: *[Name and address of the insured bidder]*

* * *

Procurement procedure *[Type of procedure]*

Short description of the contract: *[subject]*

Publication (if applicable): Public Procurement Bulletin *[Date]* *[Number]*/Reference Number in APP website

* * *

With reference to the above-mentioned procedure,

We certify that *[Name of the guaranteed bidder]* has made a deposit near the *[name and address of the bank / insurance company]* at the amount of *[currency and amount both in letters and numbers]* as a condition to insure the bid submitted by the above-mentioned economic operator.

We undertake to transfer at the account of *[name of the contracting authority]* the secured amount, within 15 (fifteen) days from your simple first written request, without asking explanations, on condition that the request mentions the non - fulfillment of one of the following conditions:

- The bidder has withdrawn or altered the bid, after the deadline for bids' submission, or prior to the deadline, if so specified in the bid documents;
- The bidder has refused to sign the procurement contract when required by the contracting authority;
- The bidder has not submitted the contract insurance, after being awarded, or has failed in meeting any other condition before signing the contract, as defined in the bid documents.

This Insurance is valid for the period of time indicated in the *[contract notification or invitation to bid]*

[Bank/insurance company representative]

Appendix 5

LIST OF CONFIDENTIAL INFORMATION

[Appendix to be completed by the economic operator, in applicable]

LIST OF CONFIDENTIAL INFORMATION

(Write down the information you wish to remain confidential)

Type, nature of information to be kept confidential	Number of pages and points in the STD you wish to remain confidential	Reasons for keeping this information confidential	Deadline for keeping this information confidential

ATTENTION

Any data that has not been registered as confidential shall be deemed to have been granted the consent of the holder of such information and the Contracting Authority shall not be liable for the disclosure of such information.

It is not considered as constituting a commercial secret the information that should be made public under the law, that is related to a violation of the law or that is to be published on the basis of good commercial practices and principles of commercial ethics. The dissemination of this information is considered legitimate, if this act is intended to protect the public interest.

Bidder Representative

Signature

Seal

Appendix 6

[Annex to be completed by the Economic Operator]

STATEMENT ON COMPLETION OF TECHNICAL SPECIFICATIONS

Statement of the economic operator participating in the public procurement procedure, organized on _____ by the Contracting Authority _____ with subject _____ with a limit fund of _____.

I, the undersigned _____, in the quality of _____ of the

Legal person _____ hereby declare that:

We meet all the technical specifications set forth in the tender documents and we certify this with documents and certificates (if requested by the contracting authority), submitted attached with this statement.

Date of statement delivery _____

Bidder's Representative

Signature

Seal

Appendix 7

[Appendix to be completed by the economic operator]

STATEMENT

On conflict of interest

Of the economic operator participating in the public procurement procedure organized on _____ by the Contracting Authority _____ with subject _____ with a limit fund of _____

Conflict of interest is the state of conflict between the public duty and private interests of an official, where he has private interests, direct or indirect ones which affect, are likely to affect or appear to affect the unfair carrying out of his public duties and responsibilities.

In application of Article 21, point 1, of Law No. 9367, dated 7.4.2005, the categories of officials stipulated in Chapter III, Section II, that are absolutely forbidden to directly or indirectly benefit from the concluding of contracts , one party of which is a public institution are:

- President of Republic, Prime Minister, Deputy Prime Minister, Ministers or Deputy Ministers, Members of Parliament, Justices of Constitutional Court, Justices of High Court, Chair of High State Audit, Prosecutor General, Ombudsman, Members of the Central Election Commission, Members of High Council of Justice or Inspector General of the High Inspectorate of Disclosure and Audit of Assets, Members of Regulatory Entities, (Supervision Council of Bank of Albania, including the Governor and Deputy Governor; of competition, telecommunication; electricity; water supply; insurance, bonds, media), Secretaries General of central institutions as well as every other public official in each public institution whose position is equivalent to that of General Directors.

If the official holds the position of the mayor or deputy mayor, chair or deputy chair of the commune or county council, member of the respective council or is an official of a high leading position of a local government unit, the prohibition because of the private interests of the official, stipulated in this point, is applied only to the concluding of contracts, as the case might be, with the municipality, commune or the county council where the official exercises these functions. This prohibition is also applied when one of the contract parties is a public institution, subordinate to this unit (Article 21 point 2 of law No.9367, dated 7.4.2005

The prohibitions stipulated in Article 21, points 1, 2 of Law No. 9367, dated 7.4.2005, with the relevant exceptions, are applied to the same extent to the persons related to the official which to the meaning of this law are: **the spouse, cohabitant, adult children, the parents of the official and those of his/her spouse and cohabitant.**

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I, the undersigned _____, in the capacity of the representative of the legal person _____ declare under my personal responsibility that:

I am aware of the requirements and prohibitions provided for in Law No. 9367, dated 7.4.2005 “On the prevention of conflict of interest in the course of exercise of public functions” as amended, as well as in the by-laws issued in its application by the High Inspectorate of Disclosure and Audit of Assets and in the Law No. 9643, dated 20.11.2006 “On Public Procurement”, as amended.

In accordance with the above mentioned legislation, I declare that none of the officials set out in **Chapter III, Section II** of Law No. 9367, dated 7.4.2005, and in this statement, does not possess private interests, directly or indirectly with the legal person I represent herein.

Date of statement submission

Name, Surname, Signature

Seal

Appendix 8

[Appendix to be completed by the Economic Operator]

STATEMENT ON FULFILLMENT OF THE GENERAL CRITERIA

Of the economic operator participating in the public procurement procedure organized on _____ by the Contracting Authority _____ with subject _____ with a limit fund of _____

I, the undersigned _____, in the capacity of the representative of the legal person _____ declare under my personal responsibility that:

- Economic operator _____ is registered with the National Business Center and has as its field of activity the object of the procurement. In the case when the Bidder is a non-profit organization, it must state that it is registered as a legal person under the Law No. 8788, dated 07.05.2001 "On Non-Profit Organizations".
- Economic operator _____ has not been convicted of a criminal offense, in accordance with Article 45/1 of the PPL,
- A person in the capacity of a member of an administrative body, a director or a supervisor, a shareholder or a partner, or has representative, decision-making or controlling powers within the economic operator, as follows: _____ etc. have not or have been not convicted by a final court decision for any of the offenses set forth in article 45/1 of LPP³.
- Economic operator _____ has not been sentenced by a final court decision for acts related to professional activity,
- Economic operator _____ is not in the process of bankruptcy (active Status),

³ Authorize the Contracting Authority to make the appropriate verifications of the judicial status of the persons stated in this Declaration.

** Note: The information to be completed and belongs to the person / s for whom the data will be reflected according to the above point in this Declaration, for the purpose of verification by the CA, must be complete including: paternity / motherhood / date of birth of the person (s) marked according to the above point and place of birth.*

Standard Tender Documents

(1) I authorize the Contracting Authority to make the relevant verifications of the judicial status of the persons declared in this Declaration

- Economic operator _____ has paid all the fees for the payment of taxes
And social security contributions, according to the legislation in force.

In any case, the contracting authority has the right to carry out the necessary verifications on the authenticity of the information declared by the economic operator as above.

Date of submission of statement

Name, Surname, Signature

Seal

Appendix 8/1

[Appendix to be completed by the Economic Operator]

STATEMENT ON THE ENFORCEMENT OF THE LEGAL PROVISIONS IN LABOR RELATIONS

Statement of the Economic Operator participating in the procurement procedure to take place on _____ by the Contracting Authority _____ with object _____ and with limit fund _____.

I, the undersigned _____ in the capacity of the _____ of the economic operator _____, hereby declare under my sole responsibility that:

- The economic operator _____ guarantees the protection of the right to employment and occupation from any form of discrimination provided for by the applicable labor legislation.
- The Economic Operator _____ has the relevant employment contracts with its employees and guarantees safety and health measures for all and, in particular, for vulnerable groups, based on applicable labor legislation.
- The economic operator _____ has no legal measure in force, established by the State Inspectorate of Labor and Social Services (ISHPSHSH).. Where legal violations are found, the economic operator has taken the necessary measures to address them, within the time limits set by the ISHPSHSH.

Date of Submission of the Statement

Bidder's representative

Signature

Seal

Appendix 9

[Appendix to be completed by the Contracting Authority]

1. GENERAL ADMISSIBILITY CRITERIA / QUALIFICATION

(SAME FOR ALL LOTS)

The Bidder shall declare that:

- a) It is registered at the National Business Center and has in its activity field the object of the procurement. In case of, the bidder is a non-profit organization, it must state that it is registered as a legal person under the Law No. 8788, dated 07.05.2001 "On Non-Profit Organizations".
- b) It is not under a process of bankruptcy (active status)
- c) It is not convicted of any criminal offences, in accordance with Article 45/1 of the PPL
- ç) It is not convicted by virtue of final court decision regarding the professional activity.
- d) It has paid all the fees for the payment of taxes and social security contributions, according to the legislation into force.

The foreign bidder must also declare that he meets all the requirements listed above by submitting a written self - declaration.

If the language used in the procedure is Albanian, then the foreign language documents must be accompanied by a notarized translation into Albanian.

In case of mergers of economic operators, each member of the group must submit the above - mentioned self - declaration.

The General Admission Criteria should not be altered by the contracting authorities.

These criteria must be met upon the submission of the written self - declaration of the subject on the day of the Bid Opening, as per Annex 8.

In any case, the contracting authority has the right to carry out the necessary verifications on the authenticity of the information declared by the economic operator, as per above.

In addition, if the bid is submitted by a group/consortium of economic operators, the following documents shall be submitted:

- a. The notarized agreement according to which the merger/consortium of economic operators has been officially established;
- b. Special power of attorney.

LOT 1- ICDVR:

2. SPECIAL QUALIFICATION CRITERIA

1. Candidate / Bidder shall submit:

a. Bid form according to Appendix 1;

b. Statement for submission of independent bids according to Annex 2/1;

c. Bid insurance, (In the amount of 2% of the Limit Fund (ALL) without VAT of the lot / lots where the Operator competes) according to Appendix 4;

ç. Statement of fulfillment of technical specifications, according to Appendix 6;

d. Statement on the Conflict of Interests according to Appendix 7;

dh. Declaration on the Guarantee of the Applicability of Legal Provisions in Labor Relations according to Annex 8/1

e. Attestation confirming the settlement of all matured electricity obligations of the energy contracts held by the economic operator registered in Albania. Note: Non-payment of electricity obligations constitutes on cause for disqualification of the economic operator, except when it turns out that the unpaid electricity obligations, confirmed in the certificate issued by the supplier, are in the process of being appealed in court.

Note*: Economic Operators, in case they offer (bids) with more than one manufacturer, EO must specify (determine) the quantity that will be brought to fulfill the contract for each manufacturer.

2. Candidate / Bidder shall submit:

2.1 Legal / Professional Capacity of Economic Operators:

a) The bidding economic operator must submit an **ISO 9001: 2015** certificate on "Quality management systems", in accordance with the procurement object, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

b) The bidding economic operator must submit an **ISO 9001: 2015** Certificate on "Quality Management Systems" or **EN ISO 13485:2016** on "Quality Management System for Medical Devices", or **SSH EN ISO 13485:2016** on "Quality Management System for Medical Devices", **of the manufacturer**, in accordance with the object of the procurement, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

c) The bidding economic operator must submit a Statement for medical materials from the bidder (distributor/manufacturer) for compliance with **MDD norms 93/42/EEC or 98/79 EC, or 2015/1535/EU, or 90/385/EEC (For Active Implants)**, when applicable, according to the Directives and classification of the Council of Europe, **attached to the copies of the relevant CE / DC (Declaration of Conformity) certificates**, original, or notarized copies, valid at the time of submission of the bid.

2.2 Economic and financial capacity:

a) Certified Copies of annual turnover declarations from the Taxation Branch for the annual turnover realized during the last 3 (three) years (**2017, 2018 and 2019**) where the average value is as **40% of the limit value*** of the lot or the amount of lots for which the operator competes.

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***Note*:** For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value will be applied over the total amount of the expected contract value for the lots competing.

3.3 Technical capacity

a) Previous similar supplies from the economic operator in a value of **40% of the Limit Fund* of the lot or the amount of lots for which the operator competes, and which has been realized during the last three years from the date of opening the bids of this procurement procedure.**

- As evidence of previous experience with a public entity, the relevant contract(s) accompanied with an attestation certifying its successful realization, is required.
- In the case of previous experience with the private sector, only sales tax invoices indicating clearly the dates, amounts and quantities of goods supplied will be accepted as evidence.

***Note*:** For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value (40%) will be applied over the total amount of the expected contract value for the lots competing.

b) A statement of the bidder on the origin of the goods (place of production and manufacturing company) is required for each item; for the fulfillment of their expiration date, as well as well as respecting of the technical specifications of the bidding lot/lots.

Note: The expiration date for medical materials subject to this procurement procedure, on the day of delivery of the goods must be not less than 1/2 of the time between the date of manufacture and that of expiration.

c) For all the offered articles should be presented **Catalogs, including the detailed technical specifications for each item (*parts of the catalog that contain name and detailed technical specifications of the item offered*). The economic operator must mark in the relevant catalog the products it offers, according to the ordinal number (marked according to the article) defined in the offer form. Catalogs will only be accepted electronically through the electronic procurement system (www.app.gov.al). Catalogs must be original, or notarized copies.**

ç) The Economic Operator must submit an **Authorization from the manufacturing company / MAH / or the distributor authorized by the manufacturer, for the trade of medical materials object of the procurement. The authorization must be valid at the time of opening and submission of bids, and original or notarized copy.**

d) The economic operator must submit a **technical bid, for the required items in the form of a table, where it must be completed: Technical specifications, Name of the manufacturing company, Origin of goods, Expiration of goods, Naming of the article / product catalog, No. of the page where the product is located, the reference number of the item (code) extracted from the manufacturer's catalog, as well as the relevant certifications for the products.**

Note:

BEC (Bid Evaluation Commission) reserves the right to verify data submitted by bidders.

All documents must be originals or notarized copies. Cases of non-submission of a document, or of false and inaccurate document, are considered as conditions for disqualification.

Note ²:

- **For foreign economic operators meeting the criteria set out in these STDs, regarding the Special Qualification Criteria, related to legal documents issued by public institutions in the Republic of Albania or equivalent legal institutions in other countries, if the documents required or equivalent do not exist according to the provisions of its domestic law, then they must submit their own statements in compliance with the required criterion. In the submitted statement they must declare the institution that covers the field of activity for which the declaration is made and they must make public in the declaration, the web link of the institution that covers the field of activity, in case of verification by BEC.**
- **For foreign economic operators registered in the member states of the Hague Convention (5 October 1961), the documents issued must contain the Apostille seal (stamp) in accordance with law no. 9060, dated 8.5.2003 "On the accession of the Republic of Albania to the Convention on the Abolition of the Requirement for the Legalization of Foreign Official Documents".**
- **For foreign economic operators who have registered in countries that have not ratified The Hague Convention dated 05.10.1961 on "Removing the Request for Diplomatic and Consular Legalization of Foreign Official Documents", the legalization of these documents should be done in the respective embassies, consulates or offices from the country of origin.**

LOT 2 - PACEMAKER VVIR AND DDDR

2. SPECIAL QUALIFICATION CRITERIA

1. Candidate / Bidder shall submit:

- a. Bid form according to Appendix 1;**
- b. Statement for submission of independent bids according to Annex 2/1;**
- c. Bid insurance, (In the amount of 2% of the Limit Fund (ALL) without VAT of the lot / lots where the Operator competes) according to Appendix 4;**
- d. Statement of fulfillment of technical specifications, according to Appendix 6;**
- dh. Declaration on the Conflict of Interests according to Appendix 7;**
- dh. Declaration on the Guarantee of the Applicability of Legal Provisions in Labor Relations according to Annex 8/1**
- e. Attestation confirming the settlement of all matured electricity obligations of the energy contracts held by the economic operator registered in Albania. Note: Non-payment of electricity obligations constitutes on cause for disqualification of the economic operator, except when it turns out that the unpaid electricity obligations, confirmed in the certificate issued by the supplier, are in the process of being appealed in court.**

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Note*: Economic Operators, in case they offer (bids) with more than one manufacturer, EO must specify (determine) the quantity that will be brought to fulfill the contract for each manufacturer.

2. Candidate / Bidder shall submit:

2.1 Legal / Professional Capacity of Economic Operators:

a) The bidding economic operator must submit an **ISO 9001: 2015** certificate on "Quality management systems", in accordance with the procurement object, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

b) The bidding economic operator must submit an **ISO 9001: 2015** Certificate on "Quality Management Systems" or **EN ISO 13485:2016** on "Quality Management System for Medical Devices", or **SSH EN ISO 13485:2016** on "Quality Management System for Medical Devices", **of the manufacturer**, in accordance with the object of the procurement, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

c) The bidding economic operator must submit a Statement for medical materials from the bidder (distributor/manufacturer) for compliance with **MDD norms 93/42/EEC or 98/79 EC, or 2015/1535/EU, or 90/385/EEC (For Active Implants)**, when applicable, according to the Directives and classification of the Council of Europe, **attached to the copies of the relevant CE / DC (Declaration of Conformity) certificates**, original, or notarized copies, valid at the time of submission of the bid.

2.2 Economic and financial capacity:

a) Certified Copies of annual turnover declarations from the Taxation Branch for the annual turnover realized during the last 3 (three) years (**2017, 2018 and 2019**) where the average value is as **40% of the limit value*** of the lot or the amount of lots for which the operator competes.

***Note*:** For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value will be applied over the total amount of the expected contract value for the lots competing.

3.3 Technical capacity

a) Previous similar supplies from the economic operator in a value of **40% of the Limit Fund* of the lot or the amount of lots** for which the operator competes, and which has been realized during the last three years from the date of opening the bids of this procurement procedure.

- As evidence of previous experience with a public entity, the relevant contract(s) accompanied with an attestation certifying its successful realization, is required.

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- In the case of previous experience with the private sector, only sales tax invoices indicating clearly the dates, amounts and quantities of goods supplied will be accepted as evidence.

Note: For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value (40%) will be applied over the total amount of the expected contract value for the lots competing.

b) A statement of the bidder on the origin of the goods (place of production and manufacturing company) is required for each item; for the fulfillment of their expiration date, as well as well as respecting of the technical specifications of the bidding lot/lots.

Note: The expiration date for medical materials subject to this procurement procedure, on the day of delivery of the goods must be not less than 1/2 of the time between the date of manufacture and that of expiration.

c) For all the offered articles should be presented **Catalogs**, including the detailed technical specifications for each item (*parts of the catalog that contain name and detailed technical specifications of the item offered*). The economic operator must mark in the relevant catalog the products it offers, according to the ordinal number (marked according to the article) defined in the offer form. Catalogs will only be accepted electronically through the electronic procurement system (www.app.gov.al). Catalogs must be original, or notarized copies.

ç) The Economic Operator must submit an **Authorization from the manufacturing company / MAH / or the distributor authorized by the manufacturer**, for the trade of medical materials object of the procurement. The authorization must be valid at the time of opening and submission of bids, and original or notarized copy.

d) The economic operator must submit a **technical bid**, for the required items in the form of a table, where it must be completed: Technical specifications, Name of the manufacturing company, Origin of goods, Expiration of goods, Naming of the article / product catalog, No. of the page where the product is located, the reference number of the item (code) extracted from the manufacturer's catalog, as well as the relevant certifications for the products.

Note:

BEC (Bid Evaluation Commission) reserves the right to verify data submitted by bidders.

All documents must be originals or notarized copies. Cases of non-submission of a document, or of false and inaccurate document, are considered as conditions for disqualification.

Note ²:

- For foreign economic operators meeting the criteria set out in these STDs, regarding the Special Qualification Criteria, related to legal documents issued by public institutions in the Republic of Albania or equivalent legal institutions in other countries, if the documents required or equivalent do not exist according to the provisions of its domestic law, then they must submit their own statements in compliance with the required criterion. In the submitted statement they must declare the institution that covers the field of activity for which the declaration is made and they must make public in the declaration,

the web link of the institution that covers the field of activity, in case of verification by BEC.

- For foreign economic operators registered in the member states of the Hague Convention (5 October 1961), the documents issued must contain the Apostille seal (stamp) in accordance with law no. 9060, dated 8.5.2003 "On the accession of the Republic of Albania to the Convention on the Abolition of the Requirement for the Legalization of Foreign Official Documents".
- For foreign economic operators who have registered in countries that have not ratified The Hague Convention dated 05.10.1961 on "Removing the Request for Diplomatic and Consular Legalization of Foreign Official Documents", the legalization of these documents should be done in the respective embassies, consulates or offices from the country of origin.

LOT 3 - PACEMAKER WITH ANTIBIOTIC

2. SPECIAL QUALIFICATION CRITERIA

1. Candidate / Bidder shall submit:

- a. Bid form according to Appendix 1;*
- b. Statement for submission of independent bids according to Annex 2/1;*
- c. Bid insurance, (In the amount of 2% of the Limit Fund (ALL) without VAT of the lot / lots where the Operator competes) according to Appendix 4;*
- ç. Statement of fulfillment of technical specifications, according to Appendix 6;*
- d. Statement on the Conflict of Interests according to Appendix 7;*
- dh. Declaration on the Guarantee of the Applicability of Legal Provisions in Labor Relations according to Annex 8/1*
- e. Attestation confirming the settlement of all matured electricity obligations of the energy contracts held by the economic operator registered in Albania. Note: Non-payment of electricity obligations constitutes on cause for disqualification of the economic operator, except when it turns out that the unpaid electricity obligations, confirmed in the certificate issued by the supplier, are in the process of being appealed in court.*

Note*: Economic Operators, in case they offer (bids) with more than one manufacturer, EO must specify (determine) the quantity that will be brought to fulfill the contract for each manufacturer.

2. Candidate / Bidder shall submit:

2.1 Legal / Professional Capacity of Economic Operators:

a) The bidding economic operator must submit an **ISO 9001: 2015** certificate on "Quality management systems", in accordance with the procurement object, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

b) The bidding economic operator must submit an **ISO 9001: 2015** Certificate on "Quality Management Systems" or **EN ISO 13485:2016** on "Quality Management System for Medical Devices", or **SSH EN ISO 13485:2016** on "Quality Management System for Medical Devices", of the manufacturer, in accordance with the object of the procurement, issued by a conformity

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assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

c) The bidding economic operator must submit a Statement for medical materials from the bidder (distributor/manufacturer) for compliance with **MDD norms 93/42/EEC or 98/79 EC, or 2015/1535/EU, or 90/385/EEC (For Active Implants)**, when applicable, according to the Directives and classification of the Council of Europe, **attached to the copies of the relevant CE / DC (Declaration of Conformity) certificates**, original, or notarized copies, valid at the time of submission of the bid.

2.2 Economic and financial capacity:

a) Certified Copies of annual turnover declarations from the Taxation Branch for the annual turnover realized during the last 3 (three) years (**2017, 2018 and 2019**) where the average value is as **40% of the limit value*** of the lot or the amount of lots for which the operator competes.

Note: For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value will be applied over the total amount of the expected contract value for the lots competing.

3.4 Technical capacity

a) Previous similar supplies from the economic operator in a value of **40% of the Limit Fund* of the lot or the amount of lots** for which the operator competes, and which has been realized during the last three years from the date of opening the bids of this procurement procedure.

- As evidence of previous experience with a public entity, the relevant contract(s) accompanied with an attestation certifying its successful realization, is required.
- In the case of previous experience with the private sector, only sales tax invoices indicating clearly the dates, amounts and quantities of goods supplied will be accepted as evidence.

Note: For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value (40%) will be applied over the total amount of the expected contract value for the lots competing.

b) A statement of the bidder on the origin of the goods (place of production and manufacturing company) is required for each item; for the fulfillment of their expiration date, as well as well as respecting of the technical specifications of the bidding lot/lots.

Note: The expiration date for medical materials subject to this procurement procedure, on the day of delivery of the goods must be not less than 1/2 of the time between the date of manufacture and that of expiration.

c) For all the offered articles should be presented **Catalogs**, including the detailed technical specifications for each item (*parts of the catalog that contain name and detailed technical specifications of the item offered*). The economic operator must mark in the relevant catalog the products it offers, according to the ordinal number (marked according to the article) defined in the

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offer form. Catalogs will only be accepted electronically through the electronic procurement system (www.app.gov.al). Catalogs must be original, or notarized copies.

ç) The Economic Operator must submit an **Authorization from the manufacturing company / MAH / or the distributor authorized by the manufacturer**, for the trade of medical materials object of the procurement. The authorization must be valid at the time of opening and submission of bids, and original or notarized copy.

d) The economic operator must submit a **technical bid**, for the required items in the form of a table, where it must be completed: Technical specifications, Name of the manufacturing company, Origin of goods, Expiration of goods, Naming of the article / product catalog, No. of the page where the product is located, the reference number of the item (code) extracted from the manufacturer's catalog, as well as the relevant certifications for the products.

Note:

BEC (Bid Evaluation Commission) reserves the right to verify data submitted by bidders.

All documents must be originals or notarized copies. Cases of non-submission of a document, or of false and inaccurate document, are considered as conditions for disqualification.

Note ²:

- For foreign economic operators meeting the criteria set out in these STDs, regarding the Special Qualification Criteria, related to legal documents issued by public institutions in the Republic of Albania or equivalent legal institutions in other countries, if the documents required or equivalent do not exist according to the provisions of its domestic law, then they must submit their own statements in compliance with the required criterion. In the submitted statement they must declare the institution that covers the field of activity for which the declaration is made and they must make public in the declaration, the web link of the institution that covers the field of activity, in case of verification by BEC.
- For foreign economic operators registered in the member states of the Hague Convention (5 October 1961), the documents issued must contain the Apostille seal (stamp) in accordance with law no. 9060, dated 8.5.2003 "On the accession of the Republic of Albania to the Convention on the Abolition of the Requirement for the Legalization of Foreign Official Documents".
- For foreign economic operators who have registered in countries that have not ratified The Hague Convention dated 05.10.1961 on "Removing the Request for Diplomatic and Consular Legalization of Foreign Official Documents", the legalization of these documents should be done in the respective embassies, consulates or offices from the country of origin.

LOT 4 - BIVENTRICULAR PACEMAKER (CRT-P)

2. SPECIAL QUALIFICATION CRITERIA

1. Candidate / Bidder shall submit:

a. Bid form according to Appendix I;

b. Statement for submission of independent bids according to Annex 2/I;

- c. **Bid insurance**, (In the amount of 2% of the Limit Fund (ALL) without VAT of the lot / lots where the Operator competes) according to **Appendix 4**;*
- ç. **Statement** of fulfillment of technical specifications, according to **Appendix 6**;*
- d. **Statement** on the Conflict of Interests according to **Appendix 7**;*
- dh. **Declaration** on the Guarantee of the Applicability of Legal Provisions in Labor Relations according to **Annex 8/1***
- e. **Attestation** confirming the settlement of all matured electricity obligations of the energy contracts held by the economic operator registered in Albania. **Note:** Non-payment of electricity obligations constitutes on cause for disqualification of the economic operator, except when it turns out that the unpaid electricity obligations, confirmed in the certificate issued by the supplier, are in the process of being appealed in court.*

Note*: Economic Operators, in case they offer (bids) with more than one manufacturer, EO must specify (determine) the quantity that will be brought to fulfill the contract for each manufacturer.

2. Candidate / Bidder shall submit:

2.1 Legal / Professional Capacity of Economic Operators:

- a)** The bidding economic operator must submit an **ISO 9001: 2015** certificate on "Quality management systems", in accordance with the procurement object, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).
- b)** The bidding economic operator must submit an **ISO 9001: 2015** Certificate on "Quality Management Systems" or **EN ISO 13485:2016** on "Quality Management System for Medical Devices", or **SSH EN ISO 13485:2016** on "Quality Management System for Medical Devices", **of the manufacturer**, in accordance with the object of the procurement, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).
- c)** The bidding economic operator must submit a Statement for medical materials from the bidder (distributor/manufacturer) for compliance with **MDD norms 93/42/EEC or 98/79 EC, or 2015/1535/EU, or 90/385/EEC (For Active Implants)**, when applicable, according to the Directives and classification of the Council of Europe, **attached to the copies of the relevant CE / DC (Declaration of Conformity) certificates**, original, or notarized copies, valid at the time of submission of the bid.

2.2 Economic and financial capacity:

- a)** Certified Copies of annual turnover declarations from the Taxation Branch for the annual turnover realized during the last 3 (three) years (**2017, 2018 and 2019**) where the average value is as **40% of the limit value*** of the lot or the amount of lots for which the operator competes.

***Note*:** For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value will be applied over the total amount of the expected contract value for the lots competing.

3.5 Technical capacity

a) Previous similar supplies from the economic operator in a value of **40% of the Limit Fund* of the lot or the amount of lots** for which the operator competes, and which has been realized during the last three years from the date of opening the bids of this procurement procedure.

- As evidence of previous experience with a public entity, the relevant contract(s) accompanied with an attestation certifying its successful realization, is required.
- In the case of previous experience with the private sector, only sales tax invoices indicating clearly the dates, amounts and quantities of goods supplied will be accepted as evidence.

Note: For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value (40%) will be applied over the total amount of the expected contract value for the lots competing.

b) A statement of the bidder on the origin of the goods (place of production and manufacturing company) is required for each item; for the fulfillment of their expiration date, as well as well as respecting of the technical specifications of the bidding lot/lots.

Note: The expiration date for medical materials subject to this procurement procedure, on the day of delivery of the goods must be not less than 1/2 of the time between the date of manufacture and that of expiration.

c) For all the offered articles should be presented **Catalogs**, including the detailed technical specifications for each item (*parts of the catalog that contain name and detailed technical specifications of the item offered*). The economic operator must mark in the relevant catalog the products it offers, according to the ordinal number (marked according to the article) defined in the offer form. Catalogs will only be accepted electronically through the electronic procurement system (www.app.gov.al). Catalogs must be original, or notarized copies.

ç) The Economic Operator must submit an **Authorization from the manufacturing company / MAH / or the distributor authorized by the manufacturer**, for the trade of medical materials object of the procurement. The authorization must be valid at the time of opening and submission of bids, and original or notarized copy.

d) The economic operator must submit a **technical bid**, for the required items in the form of a table, where it must be completed: Technical specifications, Name of the manufacturing company, Origin of goods, Expiration of goods, Naming of the article / product catalog, No. of the page where the product is located, the reference number of the item (code) extracted from the manufacturer's catalog, as well as the relevant certifications for the products.

Note:

BEC (Bid Evaluation Commission) reserves the right to verify data submitted by bidders.

All documents must be originals or notarized copies. Cases of non-submission of a document, or of false and inaccurate document, are considered as conditions for disqualification.

Note ²:

- For foreign economic operators meeting the criteria set out in these STDs, regarding the Special Qualification Criteria, related to legal documents issued by public institutions in the Republic of Albania or equivalent legal institutions in other countries, if the documents required or equivalent do not exist according to the provisions of its domestic law, then they must submit their own statements in compliance with the required criterion. In the submitted statement they must declare the institution that covers the field of activity for which the declaration is made and they must make public in the declaration, the web link of the institution that covers the field of activity, in case of verification by BEC.
- For foreign economic operators registered in the member states of the Hague Convention (5 October 1961), the documents issued must contain the Apostille seal (stamp) in accordance with law no. 9060, dated 8.5.2003 "On the accession of the Republic of Albania to the Convention on the Abolition of the Requirement for the Legalization of Foreign Official Documents".
- For foreign economic operators who have registered in countries that have not ratified The Hague Convention dated 05.10.1961 on "Removing the Request for Diplomatic and Consular Legalization of Foreign Official Documents", the legalization of these documents should be done in the respective embassies, consulates or offices from the country of origin.

LOT 5 - PACEMAKER MRI COMPATIBLE:

2. SPECIAL QUALIFICATION CRITERIA

1. Candidate / Bidder shall submit:

- a. Bid form according to Appendix 1;*
- b. Statement for submission of independent bids according to Annex 2/1;*
- c. Bid insurance, (In the amount of 2% of the Limit Fund (ALL) without VAT of the lot / lots where the Operator competes) according to Appendix 4;*
- ç. Statement of fulfillment of technical specifications, according to Appendix 6;*
- d. Statement on the Conflict of Interests according to Appendix 7;*
- dh. Declaration on the Guarantee of the Applicability of Legal Provisions in Labor Relations according to Annex 8/1*
- e. Attestation confirming the settlement of all matured electricity obligations of the energy contracts held by the economic operator registered in Albania. Note: Non-payment of electricity obligations constitutes on cause for disqualification of the economic operator, except when it turns out that the unpaid electricity obligations, confirmed in the certificate issued by the supplier, are in the process of being appealed in court.*

Note*: Economic Operators, in case they offer (bids) with more than one manufacturer, EO must specify (determine) the quantity that will be brought to fulfill the contract for each manufacturer.

2. Candidate / Bidder shall submit:

2.1 Legal / Professional Capacity of Economic Operators:

- a) The bidding economic operator must submit an **ISO 9001: 2015** certificate on "Quality management systems", in accordance with the procurement object, issued by a conformity

assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

b) The bidding economic operator must submit an **ISO 9001: 2015** Certificate on "Quality Management Systems" or **EN ISO 13485:2016** on "Quality Management System for Medical Devices", or **SSH EN ISO 13485:2016** on "Quality Management System for Medical Devices", **of the manufacturer**, in accordance with the object of the procurement, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

c) The bidding economic operator must submit a Statement for medical materials from the bidder (distributor/manufacturer) for compliance with **MDD norms 93/42/EEC or 98/79 EC, or 2015/1535/EU, or 90/385/EEC (For Active Implants)**, when applicable, according to the Directives and classification of the Council of Europe, **attached to the copies of the relevant CE / DC (Declaration of Conformity) certificates**, original, or notarized copies, valid at the time of submission of the bid.

2.2 Economic and financial capacity:

a) Certified Copies of annual turnover declarations from the Taxation Branch for the annual turnover realized during the last 3 (three) years (**2017, 2018 and 2019**) where the average value is as **40% of the limit value*** of the lot or the amount of lots for which the operator competes.

Note: For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value will be applied over the total amount of the expected contract value for the lots competing.

3.6 Technical capacity

a) Previous similar supplies from the economic operator in a value of **40% of the Limit Fund* of the lot or the amount of lots** for which the operator competes, and which has been realized during the last three years from the date of opening the bids of this procurement procedure.

- As evidence of previous experience with a public entity, the relevant contract(s) accompanied with an attestation certifying its successful realization, is required.
- In the case of previous experience with the private sector, only sales tax invoices indicating clearly the dates, amounts and quantities of goods supplied will be accepted as evidence.

Note: For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value (40%) will be applied over the total amount of the expected contract value for the lots competing.

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b) A statement of the bidder on the origin of the goods (place of production and manufacturing company) is required for each item; for the fulfillment of their expiration date, as well as well as respecting of the technical specifications of the bidding lot/lots.

Note: The expiration date for medical materials subject to this procurement procedure, on the day of delivery of the goods must be not less than 1/2 of the time between the date of manufacture and that of expiration.

c) For all the offered articles should be presented **Catalogs**, including the detailed technical specifications for each item (*parts of the catalog that contain name and detailed technical specifications of the item offered*). The economic operator must mark in the relevant catalog the products it offers, according to the ordinal number (marked according to the article) defined in the offer form. Catalogs will only be accepted electronically through the electronic procurement system (www.app.gov.al). Catalogs must be original, or notarized copies.

ç) The Economic Operator must submit an **Authorization from the manufacturing company / MAH / or the distributor authorized by the manufacturer**, for the trade of medical materials object of the procurement. The authorization must be valid at the time of opening and submission of bids, and original or notarized copy.

d) The economic operator must submit a **technical bid**, for the required items in the form of a table, where it must be completed: Technical specifications, Name of the manufacturing company, Origin of goods, Expiration of goods, Naming of the article / product catalog, No. of the page where the product is located, the reference number of the item (code) extracted from the manufacturer's catalog, as well as the relevant certifications for the products.

Note:

BEC (Bid Evaluation Commission) reserves the right to verify data submitted by bidders.

All documents must be originals or notarized copies. Cases of non-submission of a document, or of false and inaccurate document, are considered as conditions for disqualification.

Note ²:

- For foreign economic operators meeting the criteria set out in these STDs, regarding the Special Qualification Criteria, related to legal documents issued by public institutions in the Republic of Albania or equivalent legal institutions in other countries, if the documents required or equivalent do not exist according to the provisions of its domestic law, then they must submit their own statements in compliance with the required criterion. In the submitted statement they must declare the institution that covers the field of activity for which the declaration is made and they must make public in the declaration, the web link of the institution that covers the field of activity, in case of verification by BEC.
- For foreign economic operators registered in the member states of the Hague Convention (5 October 1961), the documents issued must contain the Apostille seal (stamp) in accordance with law no. 9060, dated 8.5.2003 "On the accession of the Republic of Albania to the Convention on the Abolition of the Requirement for the Legalization of Foreign Official Documents".
- For foreign economic operators who have registered in countries that have not ratified The Hague Convention dated 05.10.1961 on "Removing the Request for Diplomatic and Consular Legalization of Foreign Official Documents", the legalization of these

documents should be done in the respective embassies, consulates or offices from the country of origin.

LOT 6 - STENTS FOR CAROTIS AND RENAL ARTERIES

2. SPECIAL QUALIFICATION CRITERIA

1. Candidate / Bidder shall submit:

a. Bid form according to **Appendix 1**;

b. Statement for submission of independent bids according to **Annex 2/I**;

c. Bid insurance, (In the amount of 2% of the Limit Fund (ALL) without VAT of the lot / lots where the Operator competes) according to **Appendix 4**;

ç. Statement of fulfillment of technical specifications, according to **Appendix 6**;

d. Statement on the Conflict of Interests according to **Appendix 7**;

dh. Declaration on the Guarantee of the Applicability of Legal Provisions in Labor Relations according to **Annex 8/I**

e. Attestation confirming the settlement of all matured electricity obligations of the energy contracts held by the economic operator registered in Albania. **Note:** Non-payment of electricity obligations constitutes on cause for disqualification of the economic operator, except when it turns out that the unpaid electricity obligations, confirmed in the certificate issued by the supplier, are in the process of being appealed in court.

Note*: Economic Operators, in case they offer (bids) with more than one manufacturer, EO must specify (determine) the quantity that will be brought to fulfill the contract for each manufacturer.

2. Candidate / Bidder shall submit:

2.1 Legal / Professional Capacity of Economic Operators:

a) The bidding economic operator must submit an **ISO 9001: 2015** certificate on "Quality management systems", in accordance with the procurement object, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

b) The bidding economic operator must submit an **ISO 9001: 2015** Certificate on "Quality Management Systems" or **EN ISO 13485:2016** on "Quality Management System for Medical Devices", or **SSH EN ISO 13485:2016** on "Quality Management System for Medical Devices", **of the manufacturer**, in accordance with the object of the procurement, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

c) The bidding economic operator must submit a Statement for medical materials from the bidder (distributor/manufacturer) for compliance with **MDD norms 93/42/EEC or 98/79 EC, or 2015/1535/EU, or 90/385/EEC (For Active Implants)**, when applicable, according to the Directives and classification of the Council of Europe, **attached to the copies of the relevant CE / DC (Declaration of Conformity) certificates**, original, or notarized copies, valid at the time of submission of the bid.

2.2 Economic and financial capacity:

- a) Certified Copies of annual turnover declarations from the Taxation Branch for the annual turnover realized during the last 3 (three) years (**2017, 2018 and 2019**) where the average value is as **40% of the limit value*** of the lot or the amount of lots for which the operator competes.

Note: For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value will be applied over the total amount of the expected contract value for the lots competing.

3.7 Technical capacity

- a) Previous similar supplies from the economic operator in a value of **40% of the Limit Fund* of the lot or the amount of lots** for which the operator competes, and which has been realized during the last three years from the date of opening the bids of this procurement procedure.

- As evidence of previous experience with a public entity, the relevant contract(s) accompanied with an attestation certifying its successful realization, is required.
- In the case of previous experience with the private sector, only sales tax invoices indicating clearly the dates, amounts and quantities of goods supplied will be accepted as evidence.

Note: For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value (40%) will be applied over the total amount of the expected contract value for the lots competing.

- b) A statement of the bidder on the origin of the goods (place of production and manufacturing company) is required for each item; for the fulfillment of their expiration date, as well as well as respecting of the technical specifications of the bidding lot/lots.

Note: The expiration date for medical materials subject to this procurement procedure, on the day of delivery of the goods must be not less than 1/2 of the time between the date of manufacture and that of expiration.

- c) For all the offered articles should be presented **Catalogs**, including the detailed technical specifications for each item (*parts of the catalog that contain name and detailed technical specifications of the item offered*). The economic operator must mark in the relevant catalog the products it offers, according to the ordinal number (marked according to the article) defined in the offer form. Catalogs will only be accepted electronically through the electronic procurement system (www.app.gov.al). Catalogs must be original, or notarized copies.

- c) The Economic Operator must submit an **Authorization from the manufacturing company / MAH / or the distributor authorized by the manufacturer**, for the trade of medical materials object of the procurement. The authorization must be valid at the time of opening and submission of bids, and original or notarized copy.

- d) The economic operator must submit a **technical bid**, for the required items in the form of a table, where it must be completed: Technical specifications, Name of the manufacturing company,

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Origin of goods, Expiration of goods, Naming of the article / product catalog, No. of the page where the product is located, the reference number of the item (code) extracted from the manufacturer's catalog, as well as the relevant certifications for the products.

Note:

BEC (Bid Evaluation Commission) reserves the right to verify data submitted by bidders.

All documents must be originals or notarized copies. Cases of non-submission of a document, or of false and inaccurate document, are considered as conditions for disqualification.

Note ²:

- **For foreign economic operators meeting the criteria set out in these STDs, regarding the Special Qualification Criteria, related to legal documents issued by public institutions in the Republic of Albania or equivalent legal institutions in other countries, if the documents required or equivalent do not exist according to the provisions of its domestic law, then they must submit their own statements in compliance with the required criterion. In the submitted statement they must declare the institution that covers the field of activity for which the declaration is made and they must make public in the declaration, the web link of the institution that covers the field of activity, in case of verification by BEC.**
- **For foreign economic operators registered in the member states of the Hague Convention (5 October 1961), the documents issued must contain the Apostille seal (stamp) in accordance with law no. 9060, dated 8.5.2003 "On the accession of the Republic of Albania to the Convention on the Abolition of the Requirement for the Legalization of Foreign Official Documents".**
- **For foreign economic operators who have registered in countries that have not ratified The Hague Convention dated 05.10.1961 on "Removing the Request for Diplomatic and Consular Legalization of Foreign Official Documents", the legalization of these documents should be done in the respective embassies, consulates or offices from the country of origin.**

LOT 7 - CORONARY DRUG-ELUTING STENT WITH BIOABSORBABLE POLYMER COATING FOR RAPID ENDOTHELIAL (3RD GENERATION):

2. SPECIAL QUALIFICATION CRITERIA

1. Candidate / Bidder shall submit:

- a. Bid form** according to **Appendix 1**;
- b. Statement** for submission of independent bids according to **Annex 2/1**;
- c. Bid insurance**, (In the amount of 2% of the Limit Fund (ALL) without VAT of the lot / lots where the Operator competes) according to **Appendix 4**;
- ç. Statement** of fulfillment of technical specifications, according to **Appendix 6**;
- d. Statement** on the Conflict of Interests according to **Appendix 7**;
- dh. Declaration** on the Guarantee of the Applicability of Legal Provisions in Labor Relations according to **Annex 8/1**
- e. Attestation** confirming the settlement of all matured electricity obligations of the energy contracts held by the economic operator registered in Albania. **Note:** Non-payment of electricity obligations constitutes on cause for disqualification of the economic operator, except when it turns out that the unpaid electricity obligations, confirmed in the certificate issued by the supplier, are in the process of being appealed in court.

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Note*: Economic Operators, in case they offer (bids) with more than one manufacturer, EO must specify (determine) the quantity that will be brought to fulfill the contract for each manufacturer.

2. Candidate / Bidder shall submit:

2.1 Legal / Professional Capacity of Economic Operators:

a) The bidding economic operator must submit an **ISO 9001: 2015** certificate on "Quality management systems", in accordance with the procurement object, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

b) The bidding economic operator must submit an **ISO 9001: 2015** Certificate on "Quality Management Systems" or **EN ISO 13485:2016** on "Quality Management System for Medical Devices", or **SSH EN ISO 13485:2016** on "Quality Management System for Medical Devices", **of the manufacturer**, in accordance with the object of the procurement, issued by a conformity assessment body, accredited by the national accreditation body or by the international accreditation body, recognized by the Republic of Albania. The certificate must be valid at the time of the tender (time of submission of the bid).

c) The bidding economic operator must submit a Statement for medical materials from the bidder (distributor/manufacturer) for compliance with **MDD norms 93/42/EEC or 98/79 EC, or 2015/1535/EU, or 90/385/EEC (For Active Implants)**, when applicable, according to the Directives and classification of the Council of Europe, **attached to the copies of the relevant CE / DC (Declaration of Conformity) certificates**, original, or notarized copies, valid at the time of submission of the bid.

2.2 Economic and financial capacity:

a) Certified Copies of annual turnover declarations from the Taxation Branch for the annual turnover realized during the last 3 (three) years (**2017, 2018 and 2019**) where the average value is as **40% of the limit value*** of the lot or the amount of lots for which the operator competes.

***Note*:** For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value will be applied over the total amount of the expected contract value for the lots competing.

3.8 Technical capacity

a) Previous similar supplies from the economic operator in a value of **40% of the Limit Fund* of the lot or the amount of lots** for which the operator competes, and which has been realized during the last three years from the date of opening the bids of this procurement procedure.

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- As evidence of previous experience with a public entity, the relevant contract(s) accompanied with an attestation certifying its successful realization, is required.
- In the case of previous experience with the private sector, only sales tax invoices indicating clearly the dates, amounts and quantities of goods supplied will be accepted as evidence.

***Note*:** For the purposes of calculating the value required under this criterion, 40% shall be applied to the value of the limit fund provided under the expected quantities of contracts, referred to as the expected Value of the contracts specified in point: 2.12 / Section 2 of the STDs.*

When competing for more than 1 lot, the average value (40%) will be applied over the total amount of the expected contract value for the lots competing.

b) A statement of the bidder on the origin of the goods (place of production and manufacturing company) is required for each item; for the fulfillment of their expiration date, as well as well as respecting of the technical specifications of the bidding lot/lots.

Note: The expiration date for medical materials subject to this procurement procedure, on the day of delivery of the goods must be not less than 1/2 of the time between the date of manufacture and that of expiration.

c) For all the offered articles should be presented **Catalogs**, including the detailed technical specifications for each item (*parts of the catalog that contain name and detailed technical specifications of the item offered*). The economic operator must mark in the relevant catalog the products it offers, according to the ordinal number (marked according to the article) defined in the offer form. Catalogs will only be accepted electronically through the electronic procurement system (www.app.gov.al). Catalogs must be original, or notarized copies.

ç) The Economic Operator must submit an **Authorization from the manufacturing company / MAH / or the distributor authorized by the manufacturer**, for the trade of medical materials object of the procurement. The authorization must be valid at the time of opening and submission of bids, and original or notarized copy.

d) The economic operator must submit a **technical bid**, for the required items in the form of a table, where it must be completed: Technical specifications, Name of the manufacturing company, Origin of goods, Expiration of goods, Naming of the article / product catalog, No. of the page where the product is located, the reference number of the item (code) extracted from the manufacturer's catalog, as well as the relevant certifications for the products.

Note:

BEC (Bid Evaluation Commission) reserves the right to verify data submitted by bidders.

All documents must be originals or notarized copies. Cases of non-submission of a document, or of false and inaccurate document, are considered as conditions for disqualification.

Note ²:

- For foreign economic operators meeting the criteria set out in these STDs, regarding the Special Qualification Criteria, related to legal documents issued by public institutions in the Republic of Albania or equivalent legal institutions in other countries, if the documents required or equivalent do not exist according to the provisions of its domestic law, then they must submit their own statements in compliance with the required criterion. In the submitted statement they must declare the institution that covers the field

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of activity for which the declaration is made and they must make public in the declaration, the web link of the institution that covers the field of activity, in case of verification by BEC.

- For foreign economic operators registered in the member states of the Hague Convention (5 October 1961), the documents issued must contain the Apostille seal (stamp) in accordance with law no. 9060, dated 8.5.2003 "On the accession of the Republic of Albania to the Convention on the Abolition of the Requirement for the Legalization of Foreign Official Documents".
- For foreign economic operators who have registered in countries that have not ratified The Hague Convention dated 05.10.1961 on "Removing the Request for Diplomatic and Consular Legalization of Foreign Official Documents", the legalization of these documents should be done in the respective embassies, consulates or offices from the country of origin.

Appendix 10**LOT 1 – ICDVR:****TECHNICAL SPECIFICATIONS****Special specifications:**

No.	Designation (Medical Devices)	Unit
1*	ICD VR- single chamber implantable defibrillator with defibrillation lead, Peel able Percutaneous Lead 7F Introducer and technical support during implantation ICD-VR, ICD VR – single chamber implantable defibrillator including the following features: - maximum delivered energy at least 35 Joules, algorithms for discrimination of SVTs from VTs algorithm for monitoring lead integrity with patient alert and ability of automatic reprogramming of VF detection parameters in case of alert, trends for heart variability, daily heart rate and daily activity, 3 arrhythmia detection zones (VT, fast VT and VF) , programmable Active Can, sound or vibration alarm in case or battery depletion or any other condition, lead fracture, diagnostics features: episodes, markers and EMG Defibrillation lead, steroid, active fixation, with 2 defibrillation coils, choice of different length, Sheath-introducer peel away for introducing electrode (including guide wire, syringe, dilator, needle and introducer).	piece
2*	ICD-DR – dual chamber implantable defibrillator with compatible defibrillation lead, compatible atrial lead and 2 sheath (9 and 8 sheath) and technical support during imp ICD-DR – dual chamber implantable defibrillator with compatible defibrillation leads with the characteristics: Maximum delivered energy for HV therapy not less than 35J for all shocks, Arrhythmia detection in 3 zones (VT, FVT and VF), ATP therapy delivered before and during the capacitor charging, Automatic pacing mode switch from AAI(R) to DDD(R) and vice versa or algorithm for RV pacing minimization, Wireless communication with programmer, Programmable active SVC coil and active can for VF shock delivery, SVT discriminator based on far-field morphology, At least 2 algorithms for reducing unnecessary shocks in addition to SVT discriminators, sound or vibration alarm in case or battery depletion or any other condition	piece
3	PEEL WAY	piece
4	Pacing system analyzer (PSA) restiriliable patients' cable compatible with programmer	piece
5	Paper for programmer	piece

For articles no. 1 and 2 of Lot 1, VAT is excluded as they are implantable materials (Law no. 92/2014, dated 27.04.2014 "On Value Added Tax in the Republic of Albania", Art. 51)

GENERAL TECHNICAL SPECIFICATIONS:

- Expiration Date: The expiration date on the day of delivery of the goods must be not less than 1/2 of the time between the date of production and that of expiration.
- Self-declaration for medical materials is required from the bidder (distributor/manufacturer) for compliance with MDD norms 93/42/EEC or 98/79 / EC or 2015/1535/EU, or 90/385 / EEC (For Active Implants), when applicable, where applicable, under Council of Europe Directives and classification, attached to copies of certificates CE / DC (Declaration of conformity), original or notarized copies, valid at the time of submission.
- Authorization from MAH / official manufacturer / Distributor.
- Original or notarized catalogs for all items and mark the items offered.
- Adhere to the technical specifications required by the services for each item.

LOT 2 - PACEMAKER VVIR AND DDDR:**TECHNICAL SPECIFICATIONS****Special specifications:**

No.	Designation (Medical Devices)	Unit
1*	Pacemaker VVIR type with lead. Single chamber pacemaker with programmable pacing polarity (unipolar and bipolar), amplitude threshold test, lead impedance trend (graph of daily measured lead impedance vs. time), and automatic pacing polarity switch from bipolar to unipolar pacing in case that measured lead impedance is out of programmable range (for example in case of lead fracture), including bipolar lead	piece
2*	Pacemaker DDDR type with leads Dual chamber pacemaker rate responsive with: programmable pacing polarity (unipolar and bipolar), amplitude threshold test, mode switch to VVIR pacing mode, lead impedance trend (graph of daily measured lead impedance vs. time including bipolar lead storage of intracardiac electrograms (EGM storage), including atrial and ventricular bipolar leads with body diameter less than 2.2 mm, from them 10% with active fixation and 90% with passive fixation	piece
3	Sheeth-introducer peel away for introducing permanent pacemaker electrode (including guide wire, syringe, dilator, needle and introducer 8 F)	piece
4	Electrodes for temporary pacing with external pacemaker 5 or 6 F	piece
5	Paper for programmer	piece
6	Disposable large alligator clip style extension with safe connect used for temporary pacing procedures/resterilized)	piece
7	External pacemaker single chamber	piece
8	Pacing system analyzer (PSA) restiriliable patients' cable compatible with programmer	piece

For articles no. 1 and 2 of Lot 2, VAT is excluded as they are implantable materials (Law no. 92/2014, dated 27.04.2014 "On Value Added Tax in the Republic of Albania", Art. 51)

GENERAL TECHNICAL SPECIFICATIONS:

- Expiration Date: The expiration date on the day of delivery of the goods must be not less than 1/2 of the time between the date of production and that of expiration.
- Self-declaration for medical materials is required from the bidder (distributor/manufacturer) for compliance with MDD norms 93/42/EEC or 98/79 / EC or 2015/1535/EU, or 90/385 / EEC (For Active Implants), when applicable, where applicable, under Council of Europe Directives and classification, attached to copies of certificates CE / DC (Declaration of conformity), original or notarized copies, valid at the time of submission.
- Authorization from MAH / official manufacturer / Distributor.
- Original or notarized catalogs for all items and mark the items offered.
- Adhere to the technical specifications required by the services for each item.

LOT 3 - PACEMAKER WITH ANTIBIOTIC**TECHNICAL SPECIFICATIONS****Special specifications:**

No.	Designation (Medical Devices)	Unit
	Pacemaker with Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection.	

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1*	Pacemaker VVIR with active leads with Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection. Single chamber pacemaker with programmable pacing polarity (unipolar and bipolar), amplitude threshold test, lead impedance trend (graph of daily measured lead impedance vs. time), and automatic pacing polarity switch from bipolar to unipolar pacing in case that measured lead impedance is out of programmable range (for example in case of lead fracture), recording and storage of IEGM. Steroid eluting ventricular pacing lead with active fixation. Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection. + possibility of full body absorption + elution of minocycline and rifampicin + possibility of multiple envelope size choice.	cope
2*	Pacemaker DDDR with corresponding active leads with Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection. Dual chamber pacemaker rate responsive with: mode switch algorithm to reduce unnecessary ventricular pacing, automatic active capture control in atrium and ventricle depending on measured pacing threshold, programmable pacing polarity (unipolar and bipolar), amplitude threshold test, mode switch to VVIR/DDIR pacing mode, lead impedance trend (graph of daily measured lead impedance vs. time including bipolar lead storage of intracardiac electrograms, EGM storage. Atrial and ventricular Steroid eluting pacing lead with active fixation. Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection. + possibility of full body absorption + elution of minocycline and rifampicin + possibility of multiple envelope size choice.	cope

For articles of Lot 3, VAT is excluded as they are implantable materials (Law no. 92/2014, dated 27.04.2014 "On Value Added Tax in the Republic of Albania", Art. 51)

GENERAL TECHNICAL SPECIFICATIONS:

- Expiration Date: The expiration date on the day of delivery of the goods must be not less than 1/2 of the time between the date of production and that of expiration.
- Self-declaration for medical materials is required from the bidder (distributor/manufacturer) for compliance with MDD norms 93/42/EEC or 98/79 / EC or 2015/1535/EU, or 90/385 / EEC (For Active Implants), when applicable, where applicable, under Council of Europe Directives and classification, attached to copies of certificates CE / DC (Declaration of conformity), original or notarized copies, valid at the time of submission.
- Authorization from MAH / official manufacturer / Distributor.
- Original or notarized catalogs for all items and mark the items offered.
- Adhere to the technical specifications required by the services for each item.

LOTI 4 - BIVENTRICULAR PACEMAKER (CRT-P):

TECHNICAL SPECIFICATIONS

Special specifications:

No.	Designation (Medical Devices)	Unit
1*	Biventricular pacemaker (CRT-P) Compound of: 1- CRT Device; 2- Active Atrial Lead; 3- active Ventricular Lead; 4- CS Lead unipolar/bipolar; 5- CS cannulation catheter set; 6- Venogram Balloon catheter for coronary sinus; 7- Introducer 3pcs; 8- technical support and PROCTOR during implantation. CRT-P device including the following features: 1-Separate programming of pacing parameters (amplitude, pulse width) for LV and RV, at least 4 or 5 different programmable vectors for LV lead pacing , Programmable interventricular stimulation interval, Automatic lead polarity switch from bipolar to unipolar in case of lead impedance out of preset range, Possibility of parallel printing of diagnostic trends such as AT/AF daily burden, percentage of pacing, Algorithm for suppression atrial fibrillation by atrial pacing in sinus rhythm, Pulmonary congestion detection and monitoring, 2-Steroid eluting atrial pacing lead with active fixation, 3-Steroid eluting ventricular pacing lead with active fixation, 4-Bipolar steroid eluting lead for left ventricle stimulation through coronary sinus. Implantation over the wire, possibility of choice of different distal end curves 5-Catheter for LV introduction into coronary sinus, possibility of choice of different distal end curves.6- Accessory set for LV introduction into coronary sinus which consists of : guidewire, slitter tool, syringe and torque,7-Balloon catheter for coronary sinus venogram with possibility of introduction over-the-wire, 8- 3 Sheath-introducer peel away for introducing electrode (including guide wire, syringe, dilator, needle and introducer), 2 size 7-8 F, one size 9 F.	Piece

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2*	Biventricular defibrillator (CRT-D) with corresponding leads (compatible right ventricular lead, atrial lead, left ventricular lead, Coronary Sinus cannulation set, Balloon catheter for CS) and technical support during implantation and proctor. CRT-D device including the following features: Arrhythmia detection in 3 zones (VT, FVT and VF), ATP therapy delivered before and during the capacitor charging, Independent programming of LV and RV pacing parameters, Independent dual zone rate response programming for normal workload and high physical exercise or is single slope, Minimum 3 pacing vectors in LV+, Algorithm for ensuring CRT during ventricular sense events or algorithm synchronizes LV pacing with RV intrinsic, Programmability of at least 2 different RV sensing vectors for VT/VF detection, Patient sound alarm or vibration in case of battery depletion and lead dysfunction, SVT discriminator based on far-field morphology, sound or vibration alarm in case of battery depletion or any other condition.	Piece
3	Sub selection catheter for LV Lead introduction into target vein with angled distal	Piece
4	Pacing system analyzer (PSA) restiriliable patients' cable compatible with programmer	Piece
5	Paper for programmer	Piece
6	left ventricular lead, different size AND curve,	Piece
7	Catheter for LV entry into the coronary sinus, with the possibility of choosing different distal end curves	Piece
8	MULTI POINT biventricular DDDR A FIB pacemaker, storage of intracardiac electrograms in the device memory for 14 minutes, with automatic switching to the rest (sleep) parameters based on the patient activity, algorithm for atrial fibrillation suppression by atrial pacing at sinus rhythm, special frequency stimulation while changing the operating mode, algorithm for maintenance biventricular stimulation in case of changes at the av interval, pulmonary congestion detection and monitoring, algorithms for optimization of AV, PV and VV delays, longevity of more than 6 years with 100% DDD MPP pacing, 60 ppm, A/RV/LV1/LV2 = 2.5 V/0.4 MS, 500 Ω . Compatible atrial and pacing lead with active or passive fixation with minimum introducer of 7F. Compatible LV Electrode: Quadripolar steroid eluting lead for left ventricle stimulation through coronary sinus. Implantation over the wire, possibility of choice of different distal end curves, minimum introducer of 5 F, minimum 3 different curve options. Catheter for LV introduction into coronary sinus, possibility of choice of different distal end curves Accessory set for LV introduction into coronary sinus which consists of: guidewire, slitter tool, syringe and torque	Piece

For articles of Lot 4, VAT is excluded as they are implantable materials (Law no. 92/2014, dated 27.04.2014 "On Value Added Tax in the Republic of Albania", Art. 51)

GENERAL TECHNICAL SPECIFICATIONS:

- Expiration Date: The expiration date on the day of delivery of the goods must be not less than 1/2 of the time between the date of production and that of expiration.
- Self-declaration for medical materials is required from the bidder (distributor/manufacturer) for compliance with MDD norms 93/42/EEC or 98/79 / EC or 2015/1535/EU, or 90/385 / EEC (For Active Implants), when applicable, where applicable, under Council of Europe Directives and classification, attached to copies of certificates CE / DC (Declaration of conformity), original or notarized copies, valid at the time of submission.
- Authorization from MAH / official manufacturer / Distributor.
- Original or notarized catalogs for all items and mark the items offered.

LOTI 5 - PACEMAKER MRI COMPATIBLE:

TECHNICAL SPECIFICATIONS

Special specifications:

No.	Designation (Medical Devices)	Unit
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1	VVIR pacemaker with leads, MRI compatible: (full body scan) VVIR - FULL BODY MRI 1.5T pacemaker, storage of intracardiac electrograms, with automatic switching to the rest (sleep) parameters based on the patient activity, with programmable pacing polarity (unipolar and bipolar), impedance trend (graph of daily measured lead impedance vs. time), and automatic pacing polarity switch from bipolar to unipolar pacing in case that measured lead impedance is out of programmable range including bipolar lead, longevity of more than 14 years with 60 stimulations in minute at 2.5V 100% stimulation 0,4ms pulse width. Compatible pacing lead with active or passive fixation with minimum introducer of 7F. Sheath-introducer peel away for introducing permanent pacemaker electrode (including guide wire, syringe, dilator, needle and introducer) of standard size from minimum 7 F.	Piece
1.1	Introducer	Piece
2	DDDR pacemaker with atrial and ventricular leads, MRI compatible: (full body scan) A FIB FULL BODY MRI 1.5T dual chamber pacemaker, storage of intracardiac electrograms, with automatic switching to the rest (sleep) parameters based on the patient activity, automatic pacing polarity switch from bipolar to unipolar pacing in case that measured lead impedance is out of programmable range including bipolar lead, Algorithm for suppression atrial fibrillation by atrial pacing in sinus rhythm, automatic algorithm to prevent unnecessary ventricular stimulation by adapting the AV delay, special frequency stimulation during mode changes (mode switch), storage of intracardiac electrograms in the device memory for 2 minutes with choice of priorities triggers, NIPS protocol, PVC Response, algorithm for terminating a PMT , longevity of more than 9 years with 60 stimulations in minute at 2.5V 100% stimulation 0,4ms pulse width with Stored EGM On. Compatible atrial a and pacing lead with active or passive fixation with minimum introducer of 7F.	Piece
3	Pacing system analyzer (PSA) restiriliabile patients' cable compatible with programmer	Piece
4	Paper for programmer	Piece
5	Disposable large alligator clip style extension with safe connect used for temporary pacing procedures/resterilized)	Piece

For Lot 5, VAT is excluded as they are implantable materials (Law no. 92/2014, dated 27.04.2014 "On Value Added Tax in the Republic of Albania", Art. 51)

GENERAL TECHNICAL SPECIFICATIONS:

- Expiration Date: The expiration date on the day of delivery of the goods must be not less than 1/2 of the time between the date of production and that of expiration.
- Self-declaration for medical materials is required from the bidder (distributor/manufacture) for compliance with MDD norms 93/42/EEC or 98/79 / EC or 2015/1535/EU, or 90/385 / EEC (For Active Implants), when applicable, where applicable, under Council of Europe Directives and classification, attached to copies of certificates CE / DC (Declaration of conformity), original or notarized copies, valid at the time of submission.
- Authorization from MAH / official manufacturer / Distributor.
Original or notarized catalogs for all items and mark the items offered.

LOTI 6 - STENTS FOR RENAL AND CAROTIS:

TECHNICAL SPECIFICATIONS

Special specifications:

No.	Designation (Medical Devices)	Unit
1	4.0 x 12 – 15 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014"guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece
2	4.0 x 16 – 19 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014"guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece
3	5.0 x 12 – 15 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014"guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece

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4	5.0 x 16 – 19 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014" guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece
5	6.0 - 8 x 14 – 16 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014" guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece
6	7.0 – 8.0 x 15 – 16 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014" guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece
7	7.0 – 8.0 x 18 – 20 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014" guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece
8	6.0 – 8.0 x 30 – 40 mm length. Self-expanding stent, rapid exchange delivery over .014" guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for carotid artery stenting.	Piece
9	37.0 – 39.0 x 30 – 40 mm length. Self-expanding stent, rapid exchange delivery over .014" guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for carotid artery stenting.	Piece
10	5.0 – 6.0 x 30 – 40 mm length. Self-expanding stent, non-tapered, rapid exchange delivery over .014" guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for carotid artery stenting.	Piece
11	7.0 – 8.0 x 40 mm length. Self-expanding stent, non-tapered, rapid exchange delivery over .014" guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for carotid artery stenting.	Piece
12	39.0-10 x 40 mm length. Self-expanding stent, non-tapered, rapid exchange delivery over .014" guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for carotid artery stenting.	Piece
13	3.5 – 5.5 mm diameter distal protection device, type filter, exchangeable over a standard .014" guidewire or incorporated on a .014" guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for embolic protection during carotid artery stenting.	Piece
14	Equal or over 5.5 mm diameter distal protection device, type filter, exchangeable over a standard .014 guidewire or incorporated on .014 guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for embolic protection during carotid artery stenting.	Piece
15	4.0 x 20 mm PTA balloon, rapid exchange delivery over .014" guidewire, 100 – 150 cm length, FDA or CE approval.	Piece
16	5.0 x 20 mm PTA balloon, rapid exchange delivery over .014" or .018" guidewire, 100 – 150 cm length, FDA or CE approval.	Piece
17	6.0 x 20 mm PTA balloon, rapid exchange delivery over .014" or .018" guidewire, 100 – 150 cm length, FDA or CE approval.	Piece
18	7.0 x 20 mm PTA balloon, rapid exchange delivery over .014" or .018" guidewire, 100 – 150 cm length, FDA or CE approval.	Piece
19	40 – 60 cm, 6F – 7F hydrophilic guiding sheath / introducer, inner diameter 2.0 – 2.5 mm, renal double curve or equivalent, .035" – .038" guidewire compatible, Cross-Cut or Tuohy-Borst valve.	Piece
20	>80 cm, 6F – 7F hydrophilic guiding sheath / introducer, inner diameter 2.0 – 2.5 mm, multipurpose curve or equivalent, .035" – .038" guidewire compatible, Cross-Cut or Tuohy-Borst valve.	Piece
21	>80 cm, 6F – 7F hydrophilic guiding sheath / introducer, inner diameter 2.0 – 2.5 mm, Hockey stick curve, or equivalent .035" – .038" guidewire compatible, Cross-Cut or Tuohy-Borst valve.	Piece
22	>80 cm, 6F – 7F hydrophilic guiding sheath / introducer, inner diameter 2.0 – 2.5 mm, straight curve, .035" – .038" guidewire compatible, Cross-Cut or Tuohy-Borst valve.	Piece
23	5F – =>100 cm, Simmons SIM2 or Bentson JB2 or Vitek curve diagnostic catheter, .035" – .038" guidewire compatible. Catheter diagnostic	Piece
24	.035" – >160 cm, hydrophilic, straight or angled soft tip guidewire.	Piece
25	Vascular Closure Device, suture mediated or clip mediated, FDA and CE approved for closure of 6F to 8F puncture femoral access size.	Piece

For articles of Lot 6, VAT is excluded as they are implantable materials (Law no. 92/2014, dated 27.04.2014 "On Value Added Tax in the Republic of Albania", Art. 51)

GENERAL TECHNICAL SPECIFICATIONS:

- Expiration Date: The expiration date on the day of delivery of the goods must be not less than 1/2 of the time between the date of production and that of expiration.
- Self-declaration for medical materials is required from the bidder (distributor/manufacturer) for compliance with MDD norms 93/42/EEC or 98/79 / EC or 2015/1535/EU, or 90/385 / EEC (For

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Active Implants), when applicable, where applicable, under Council of Europe Directives and classification, attached to copies of certificates CE / DC (Declaration of conformity), original or notarized copies, valid at the time of submission.

- Authorization from MAH / official manufacturer / Distributor.
- Original or notarized catalogs for all items and mark the items offered.

LOTI 7 - CORONARY DRUG-ELUTING STENT WITH BIOABSORBABLE POLYMER COATING FOR RAPID ENDOTHELIAL (3rd GENERATION):

TECHNICAL SPECIFICATIONS

Special specifications:

No.	Designation (Medical Devices)	Unit
	Drug-eluting stent with bioabsorbable polymer coating for rapid endothelial healing	
	Drug-eluting stent with bioabsorbable polymer for rapid healing. Obligatory characteristics: Coronary stent that releases drug (drug-eluting) made of platinum chromium alloy (PtCr), with strut thickness less than 100 µm, with the active component - cytostatic with anti-inflammatory and antiproliferative activity - Everolimus, Zotarolimus, Biolimus, bioabsorbable polymer coating that is located on the outer surface of the stent platform and is reabsorbed in less than 6 months, allowing for a complete drug elution at less than 4 months, tested in randomized, multicentric studies for their efficacy, with FDA or CE approval. CE approval for use in patients with coronary artery disease or equivalent.	
1	Diameter 2.25mm, length 7-8mm or equivalent	Piece
2	Diameter 2.25mm, length 11-12mm or equivalent	Piece
3	Diameter 2.25mm, length 15-16mm or equivalent	Piece
4	Diameter 2.25mm, length 19-20mm or equivalent	Piece
5	Diameter 2.25mm, length 23-24mm or equivalent	Piece
6	Diameter 2.25mm, length 27-28mm or equivalent	Piece
7	Diameter 2.25mm, length 31-32mm or equivalent	Piece
8	Diameter 2.25mm, length 37-38mm or equivalent	Piece
9	Diameter 2.50mm, length 7-8mm or equivalent	Piece
10	Diameter 2.50mm, length 11-12mm or equivalent	Piece
11	Diameter 2.50mm, length 15-16mm or equivalent	Piece
12	Diameter 2.50mm, length 19-20mm or equivalent	Piece
13	Diameter 2.50mm, length 23-24mm or equivalent	Piece
14	Diameter 2.50mm, length 27-28mm or equivalent	Piece
15	Diameter 2.50mm, length 31-32mm or equivalent	Piece
16	Diameter 2.50mm, length 37-38mm or equivalent	Piece
17	Diameter 2.50mm, length 47-48mm or equivalent	Piece
18	Diameter 2.75mm, length 7-8mm or equivalent	Piece
19	Diameter 2.75mm, length 11-12mm or equivalent	Piece
20	Diameter 2.75mm, length 15-16mm or equivalent	Piece
21	Diameter 2.75mm, length 19-20mm or equivalent	Piece
22	Diameter 2.75mm, length 23-24mm or equivalent	Piece
23	Diameter 2.75mm, length 27-28mm or equivalent	Piece
24	Diameter 2.75mm, length 31-32mm or equivalent	Piece
25	Diameter 2.75mm, length 37-38mm or equivalent	Piece
26	Diameter 2.75mm, length 47-48mm or equivalent	Piece
27	Diameter 3.0mm, length 7-8mm or equivalent	Piece
28	Diameter 3.0mm, length 11-12mm or equivalent	Piece
29	Diameter 3.0mm, length 15-16mm or equivalent	Piece
30	Diameter 3.0mm, length 19-20mm or equivalent	Piece
31	Diameter 3.0mm, length 23-24mm or equivalent	Piece
32	Diameter 3.0mm, length 27-28mm or equivalent	Piece

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33	Diameter 3.0mm, length 31-32mm or equivalent	Piece
34	Diameter 3.0mm, length 37-38mm or equivalent	Piece
35	Diameter 3.0mm, length 47-48mm or equivalent	Piece
36	Diameter 3.5mm, length 7-8mm or equivalent	Piece
37	Diameter 3.5mm, length 11-12mm or equivalent	Piece
38	Diameter 3.5mm, length 15-16mm or equivalent	Piece
39	Diameter 3.5mm, length 19-20mm or equivalent	Piece
40	Diameter 3.5mm, length 23-24mm or equivalent	Piece
41	Diameter 3.5mm, length 27-28mm or equivalent	Piece
42	Diameter 3.5mm, length 31-32mm or equivalent	Piece
43	Diameter 3.5mm, length 37-38mm or equivalent	Piece
44	Diameter 3.5mm, length 47-48mm or equivalent	Piece
45	Diameter 4.0mm, length 07-08mm or equivalent	Piece
46	Diameter 4.0mm, length 11-12mm or equivalent	Piece
47	Diameter 4.0mm, length 15-16mm or equivalent	Piece
48	Diameter 4.0mm, length 19-20mm or equivalent	Piece
49	Diameter 4.0mm, length 23-24mm or equivalent	Piece
50	Diameter 4.0mm, length 27-28mm or equivalent	Piece
51	Diameter 4.0mm, length 31-32mm or equivalent	Piece
52	Diameter 4.0mm, length 37-38mm or equivalent	Piece
53	Diameter 4.0mm, length 47-48mm or equivalent	Piece
54	Diameter 4.5mm, length 11-12mm or equivalent	Piece
55	Diameter 4.5mm, length 15-16mm or equivalent	Piece
56	Diameter 4.5mm, length 19-20mm or equivalent	Piece
57	Diameter 4.5mm, length 23-24mm or equivalent	Piece
58	Diameter 4.5mm, length 27-28mm or equivalent	Piece
59	Diameter 4.5mm, length 31-32mm or equivalent	Piece
60	Diameter 5.0mm, length 11-12mm or equivalent	Piece
61	Diameter 5.0mm, length 15-16mm or equivalent	Piece
62	Diameter 5.0mm, length 19-20mm or equivalent	Piece
63	Diameter 5.0mm, length 23-24mm or equivalent	Piece
64	Diameter 5.0mm, length 27-28mm or equivalent	Piece
65	Diameter 5.0mm, length 31-32mm or equivalent	Piece

For articles of Lot 7, VAT is excluded as they are implantable materials (Law no. 92/2014, dated 27.04.2014 "On Value Added Tax in the Republic of Albania", Art. 51)

GENERAL TECHNICAL SPECIFICATIONS:

- Expiration Date: The expiration date on the day of delivery of the goods must be not less than 1/2 of the time between the date of production and that of expiration.
- Self-declaration for medical materials is required from the bidder (distributor/manufacturer) for compliance with MDD norms 93/42/EEC or 98/79 / EC or 2015/1535/EU, or 90/385 / EEC (For Active Implants), when applicable, where applicable, under Council of Europe Directives and classification, attached to copies of certificates CE / DC (Declaration of conformity), original or notarized copies, valid at the time of submission.
- Authorization from MAH / official manufacturer / Distributor.
Original or notarized catalogs for all items and mark the items offered.

Appendix 11

[Appendix to be completed by the Contracting Authority in the Framework Agreement]

**PLANNING OF
CONTRACTS IN THE FRAMEWORK AGREEMENT**

<div style="text-align: center;"><input type="checkbox"/> Goods: Total number of contracts under the Framework Agreement _____</div>		
Contract number	Contract Title	Short description of the contract
01	_____	_____
02	_____	_____
03	_____	_____
...	_____	_____

Appendix 12**QUANTITY AND GRAPHICS OF DISBURSEMENT****Amount of Goods Required:****LOT 1 – ICDVR:**

No.	Designation (Medical Devices)	Unit	Quantity
1*	ICD VR- single chamber implantable defibrillator with defibrillation lead, Peel able Percutaneous Lead 7F Introducer and technical support during implantation ICD-VR, ICD VR – single chamber implantable defibrillator including the following features: - maximum delivered energy at least 35 Joules, algorithms for discrimination of SVTs from VTs algorithm for monitoring lead integrity with patient alert and ability of automatic reprogramming of VF detection parameters in case of alert, trends for heart variability, daily heart rate and daily activity, 3 arrhythmia detection zones (VT, fast VT and VF) , programmable Active Can, sound or vibration alarm in case or battery depletion or any other condition, lead fracture, diagnostics features: episodes, markers and EMG Defibrillation lead, steroid, active fixation, with 2 defibrillation coils, choice of different length, Sheath-introducer peel away for introducing electrode (including guide wire, syringe, dilator, needle and introducer).	piece	70
2*	ICD-DR – dual chamber implantable defibrillator with compatible defibrillation lead, compatible atrial lead and 2 sheath (9 and 8 sheath) and technical support during imp ICD-DR – dual chamber implantable defibrillator with compatible defibrillation leads with the characteristics: Maximum delivered energy for HV therapy not less than 35J for all shocks, Arrhythmia detection in 3 zones (VT, FVT and VF), ATP therapy delivered before and during the capacitor charging, Automatic pacing mode switch from AAI(R) to DDD(R) and vice versa or algorithm for RV pacing minimization, Wireless communication with programmer, Programmable active SVC coil and active can for VF shock delivery, SVT discriminator based on far-field morphology, At least 2 algorithms for reducing unnecessary shocks in addition to SVT discriminators, sound or vibration alarm in case or battery depletion or any other condition	piece	10
3	PEEL WAY	piece	90
4	Pacing system analyzer (PSA) restiriliable patients' cable compatible with programmer	piece	20
5	Paper for programmer	piece	10

LOT 2 - PACEMAKER VVIR AND DDDR:

No.	Designation (Medical Devices)	Unit	Quant.
1*	Pacemaker VVIR type with lead. Single chamber pacemaker with programmable pacing polarity (unipolar and bipolar), amplitude threshold test, lead impedance trend (graph of daily measured lead impedance vs. time), and automatic pacing polarity switch from bipolar to unipolar pacing in case that measured lead impedance is out of programmable range (for example in case of lead fracture), including bipolar lead	piece	500

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2*	Pacemaker DDDR type with leads Dual chamber pacemaker rate responsible with: programmable pacing polarity (unipolar and bipolar), amplitude threshold test, mode switch to VVIR pacing mode, lead impedance trend (graph of daily measured lead impedance vs. time including bipolar lead storage of intracardiac electrograms (EGM storage), including atrial and ventricular bipolar leads with body diameter less than 2.2 mm, from them 10% with active fixation and 90% with passive fixation	piece	200
3	Sheeth-introducer peel away for introducing permanent pacemaker electrode (including guide wire, syringe, dilator, needle and introducer 8 F)	piece	800
4	Electrodes for temporary pacing with external pacemaker 5 or 6 F	piece	40
5	Paper for programmer	piece	10
6	Disposable large alligator clip style extension with safe connect used for tempory pacing procedures/resterilized)	piece	10
7	External pacemaker single chamber	piece	1
8	Pacing system analyzer (PSA) restriliable patients' cable compatible with programmer	piece	20

LOT 3 - PACEMAKER WITH ANTIBIOTIC

No.	Designation (Medical Devices)	Unit	Quant.
	Pacemaker with Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection.		
1*	Pacemaker VVIR with active leads with Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection. Single chamber pacemaker with programmable pacing polarity (unipolar and bipolar), amplitude threshold test, lead impedance trend (graph of daily measured lead impedance vs. time), and automatic pacing polarity switch from bipolar to unipolar pacing in case that measured lead impedance is out of programmable range (for example in case of lead fracture), recording and storage of IEGM. Steroid eluting ventricular pacing lead with active fixation. Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection. + possibility of full body absorption + elution of minocycline and rifampicin + possibility of multiple envelope size choice.	cope	12
2*	Pacemaker DDDR with corresponding active leads with Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection. Dual chamber pacemaker rate responsible with: mode switch algorithm to reduce unnecessary ventricular pacing, automatic active capture control in atrium and ventricle depending on measured pacing threshold, programmable pacing polarity (unipolar and bipolar), amplitude threshold test, mode switch to VVIR/DDIR pacing mode, lead impedance trend (graph of daily measured lead impedance vs. time including bipolar lead storage of intracardiac electrograms, EGM storage. Atrial and ventricular Steroid eluting pacing lead with active fixation. Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection. + possibility of full body absorption + elution of minocycline and rifampicin + possibility of multiple envelope size choice.	cope	5

LOTI 4 - BIVENTRICULAR PACEMAKER (CRT-P):

No.	Designation (Medical Devices)	Unit	Quant.
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1*	<p>Biventricular pacemaker (CRT-P) Compound of: 1- CRT Device; 2- Active Atrial Lead; 3- active Ventricular Lead; 4- CS Lead unipolar/bipolar; 5- CS cannulation catheter set; 6- Venogram Balloon catheter for coronary sinus; 7- Introducer 3pcs; 8- technical support and PROCTOR during implantation.</p> <p>CRT-P device including the following features: 1-Separate programming of pacing parameters (amplitude, pulse width) for LV and RV, at least 4 or 5 different programmable vectors for LV lead pacing , Programmable interventricular stimulation interval, Automatic lead polarity switch from bipolar to unipolar in case of lead impedance out of preset range, Possibility of parallel printing of diagnostic trends such as AT/AF daily burden, percentage of pacing, Algorithm for suppression atrial fibrillation by atrial pacing in sinus rhythm, Pulmonary congestion detection and monitoring, 2-Steroid eluting atrial pacing lead with active fixation, 3-Steroid eluting ventricular pacing lead with active fixation, 4-Bipolar steroid eluting lead for left ventricle stimulation through coronary sinus. Implantation over the wire, possibility of choice of different distal end curves 5-Catheter for LV introduction into coronary sinus, possibility of choice of different distal end curves.6- Accessory set for LV introduction into coronary sinus which consists of : guidewire, slitter tool, syringe and torque,7-Balloon catheter for coronary sinus venogram with possibility of introduction over-the-wire, 8- 3 Sheath-introducer peel away for introducing electrode (including guide wire, syringe, dilator, needle and introducer), 2 size 7-8 F, one size 9 F.</p>	Piece	35
2*	<p>Biventricular defibrillator (CRT-D) with corresponding leads (compatible right ventricular lead, atrial lead, left ventricular lead, Coronary Sinus cannulation set, Balloon catheter for CS) and technical support during implantation and proctor.</p> <p>CRT-D device including the following features: Arrhythmia detection in 3 zones (VT, FVT and VF), ATP therapy delivered before and during the capacitor charging, Independent programming of LV and RV pacing parameters, Independent dual zone rate response programming for normal workload and high physical exercise or is single slope, Minimum 3 pacing vectors in LV+, Algorithm for ensuring CRT during ventricular sense events or algorithm synchronies LV pacing with RV intrinsic, Programmability of at least 2 different RV sensing vectors for VT/VF detection , Patient sound alarm or vibration in case of battery depletion and lead dysfunction , SVT discriminator based on far-field morphology, sound or vibration alarm in case or battery depletion or any other condition.</p>	Piece	5
3	Sub selection catheter for LV Lead introduction into target vein with angled distal	Piece	35
4	Pacing system analyzer (PSA) restiriliable patients' cable compatible with programmer	Piece	10
5	Paper for programmer	Piece	20
6	left ventricular lead, different size AND curve,	Piece	30
7	Catheter for LV entry into the coronary sinus, with the possibility of choosing different distal end curves	Piece	30
8	<p>MULTI POINT biventricular DDDR A FIB pacemaker, storage of intracardiac electrograms in the device memory for 14 minutes, with automatic switching to the rest (sleep) parameters based on the patient activity, algorithm for atrial fibrillation suppression by atrial pacing at sinus rhythm, special frequency stimulation while changing the operating mode, algorithm for maintenance biventricular stimulation in case of changes at the av interval, pulmonary congestion detection and monitoring, algorithms for optimization of AV, PV and VV delays, longevity of more than 6 years with 100% DDD MPP pacing, 60 ppm,</p> <p>A/RV/LV1/LV2 =2.5 V/0.4 MS, 500 Ω. Compatible atrial and pacing lead with active or passive fixation with minimum introducer of 7F. Compatible LV Electrode: Quadripolar steroid eluting lead for left ventricle stimulation through coronary sinus. Implantation over the wire, possibility of choice of different distal end curves, minimum introducer of 5 F, minimum 3 different curve options.</p> <p>Catheter for LV introduction into coronary sinus, possibility of choice of different distal end curves</p> <p>Accessory set for LV introduction into coronary sinus which consists of: guidewire, slitter tool, syringe and torque</p>	Piece	5

LOTI 5 - PACEMAKER MRI COMPATIBLE:

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No.	Designation (Medical Devices)	Unit	Quant.
1	VVIR pacemaker with leads, MRI compatible: (full body scan) VVIR - FULL BODY MRI 1.5T pacemaker, storage of intracardiac electrograms, with automatic switching to the rest (sleep) parameters based on the patient activity, with programmable pacing polarity (unipolar and bipolar), impedance trend (graph of daily measured lead impedance vs. time), and automatic pacing polarity switch from bipolar to unipolar pacing in case that measured lead impedance is out of programmable range including bipolar lead, longevity of more than 14 years with 60 stimulations in minute at 2.5V 100% stimulation 0,4ms pulse width. Compatible pacing lead with active or passive fixation with minimum introducer of 7F. Sheath-introducer peel away for introducing permanent pacemaker electrode (including guide wire, syringe, dilator, needle and introducer) of standard size from minimum 7 F.	Piece	180
1.1	Introducer	Piece	350
2	DDDR pacemaker with atrial and ventricular leads, MRI compatible: (full body scan) A FIB FULL BODY MRI 1.5T dual chamber pacemaker, storage of intracardiac electrograms, with automatic switching to the rest (sleep) parameters based on the patient activity, automatic pacing polarity switch from bipolar to unipolar pacing in case that measured lead impedance is out of programmable range including bipolar lead, Algorithm for suppression atrial fibrillation by atrial pacing in sinus rhythm, automatic algorithm to prevent unnecessary ventricular stimulation by adapting the AV delay, special frequency stimulation during mode changes (mode switch), storage of intracardiac electrograms in the device memory for 2 minutes with choice of priorities triggers, NIPS protocol, PVC Response, algorithm for terminating a PMT, longevity of more than 9 years with 60 stimulations in minute at 2.5V 100% stimulation 0,4ms pulse width with Stored EGM On. Compatible atrial a and pacing lead with active or passive fixation with minimum introducer of 7F.	Piece	70
3	Pacing system analyzer (PSA) restiriliable patients' cable compatible with programmer	Piece	20
4	Paper for programmer	Piece	20
5	Disposable large alligator clip style extension with safe connect used for temporary pacing procedures/resterilized)	Piece	20

LOTI 6 - STENTS FOR RENAL AND CAROTIS:

No.	Designation (Medical Devices)	Unit	Quant.
1	4.0 x 12 – 15 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece	2
2	4.0 x 16 – 19 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece	3
3	5.0 x 12 – 15 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece	3
4	5.0 x 16 – 19 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece	3
5	6.0 -8 x 14 – 16 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece	4
6	7.0 – 8.0 x 15 – 16 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece	3
7	7.0 – 8.0 x 18 – 20 mm Balloon expandable stent, cobalt chromium or stainless-steel alloy, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for renal artery stenting.	Piece	2
8	6.0 – 8.0 x 30 – 40 mm length. Self-expanding stent, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for carotid artery stenting.	Piece	12

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9	37.0 – 39.0 x 30 – 40 mm length. Self-expanding stent, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for carotid artery stenting.	Piece	12
10	5.0 – 6.0 x 30 – 40 mm length. Self-expanding stent, non-tapered, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for carotid artery stenting.	Piece	6
11	7.0 – 8.0 x 40 mm length. Self-expanding stent, non-tapered, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for carotid artery stenting	Piece	3
12	39.0-10 x 40 mm length. Self-expanding stent, non-tapered, rapid exchange delivery over .014“guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for carotid artery stenting.	Piece	2
13	3.5 – 5.5 mm diameter distal protection device, type filter, exchangeable over a standard .014” guidewire or incorporated on a .014” guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for embolic protection during carotid artery stenting.	Piece	15
14	Equal or over 5.5 mm diameter distal protection device, type filter, exchangeable over a standard .014 guidewire or incorporated onm .014 guidewire, deliverable through a 7F or less introducer, FDA and CE approved indication for embolic protection during carotid artery stenting.	Piece	20
15	4.0 x 20 mm PTA balloon, rapid exchange delivery over .014“guidewire, 100 – 150 cm length, FDA or CE approval.	Piece	5
16	5.0 x 20 mm PTA balloon, rapid exchange delivery over .014“or .018“guidewire, 100 – 150 cm length, FDA or CE approval.	Piece	10
17	6.0 x 20 mm PTA balloon, rapid exchange delivery over .014“or .018“ guidewire, 100 – 150 cm length, FDA or CE approval.	Piece	12
18	7.0 x 20 mm PTA balloon, rapid exchange delivery over .014“or .018” guidewire, 100 – 150 cm length, FDA or CE approval.	Piece	10
19	40 – 60 cm, 6F – 7F hydrophilic guiding sheath / introducer, inner diameter 2.0 – 2.5 mm, renal double curve or equivalent, .035” – .038” guidewire compatible, Cross-Cut or Tuohy-Borst valve.	Piece	10
20	>80 cm, 6F – 7F hydrophilic guiding sheath / introducer, inner diameter 2.0 – 2.5 mm, multipurpose curve or equivalent, .035” – .038” guidewire compatible, Cross-Cut or Tuohy-Borst valve.	Piece	20
21	>80 cm, 6F – 7F hydrophilic guiding sheath / introducer, inner diameter 2.0 – 2.5 mm, Hockey stick curve, or equivalent .035” – .038” guidewire compatible, Cross-Cut or Tuohy-Borst valve.	Piece	7
22	>80 cm, 6F – 7F hydrophilic guiding sheath / introducer, inner diameter 2.0 – 2.5 mm, straight curve, .035” – .038” guidewire compatible, Cross-Cut or Tuohy-Borst valve.	Piece	8
23	5F – >100 cm, Simmons SIM2 or Bentson JB2 or Vitek curbe diagnostic catheter, .035” – .038” guidewire compatible. Catheter diagnostic	Piece	10
24	.035” – >160 cm, hydrophilic, straight or angled soft tip guidewire.	Piece	40
25	Vascular Closure Device, suture mediated or clip mediated, FDA and CE approved for closure of 6F to 8F puncture femoral access size.	Piece	40

LOTI 7 - CORONARY DRUG-ELUTING STENT WITH BIOABSORBABLE POLYMER COATING FOR RAPID ENDOTHELIAL (3rd GENERATION):

No.	Designation (Medical Devices)	Unit	Quant.
	Drug-eluting stent with bioabsorbable polymer coating for rapid endothelial healing		
	Drug-eluting stent with bioabsorbable polymer for rapid healing. Obligatory characteristics: Coronary stent that releases drug (drug-eluting) made of platinum chromium alloy (PtCr), with strut thickness less than 100 µm, with the active component - cytostatic with anti-inflammatory and antiproliferative activity - Everolimus, Zotarolimus, Biolimus, bioabsorbable polymer coating that is located on the outer surface of the stent platform and is reabsorbed in less than 6 months, allowing for a complete drug elution at less than 4 months, tested in randomized, multicentric studies for their efficacy, with FDA or CE approval. CE approval for use in patients with coronary artery disease or equivalent.		
1	Diameter 2.25mm, length 7-8mm or equivalent	Piece	1

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2	Diameter 2.25mm, length 11-12mm or equivalent	Piece	3
3	Diameter 2.25mm, length 15-16mm or equivalent	Piece	4
4	Diameter 2.25mm, length 19-20mm or equivalent	Piece	5
5	Diameter 2.25mm, length 23-24mm or equivalent	Piece	5
6	Diameter 2.25mm, length 27-28mm or equivalent	Piece	5
7	Diameter 2.25mm, length 31-32mm or equivalent	Piece	2
8	Diameter 2.25mm, length 37-38mm or equivalent	Piece	1
9	Diameter 2.50mm, length 7-8mm or equivalent	Piece	2
10	Diameter 2.50mm, length 11-12mm or equivalent	Piece	5
11	Diameter 2.50mm, length 15-16mm or equivalent	Piece	5
12	Diameter 2.50mm, length 19-20mm or equivalent	Piece	7
13	Diameter 2.50mm, length 23-24mm or equivalent	Piece	11
14	Diameter 2.50mm, length 27-28mm or equivalent	Piece	11
15	Diameter 2.50mm, length 31-32mm or equivalent	Piece	11
16	Diameter 2.50mm, length 37-38mm or equivalent	Piece	6
17	Diameter 2.50mm, length 47-48mm or equivalent	Piece	3
18	Diameter 2.75mm, length 7-8mm or equivalent	Piece	2
19	Diameter 2.75mm, length 11-12mm or equivalent	Piece	6
20	Diameter 2.75mm, length 15-16mm or equivalent	Piece	7
21	Diameter 2.75mm, length 19-20mm or equivalent	Piece	10
22	Diameter 2.75mm, length 23-24mm or equivalent	Piece	12
23	Diameter 2.75mm, length 27-28mm or equivalent	Piece	12
24	Diameter 2.75mm, length 31-32mm or equivalent	Piece	12
25	Diameter 2.75mm, length 37-38mm or equivalent	Piece	10
26	Diameter 2.75mm, length 47-48mm or equivalent	Piece	7
27	Diameter 3.0mm, length 7-8mm or equivalent	Piece	2
28	Diameter 3.0mm, length 11-12mm or equivalent	Piece	6
29	Diameter 3.0mm, length 15-16mm or equivalent	Piece	7
30	Diameter 3.0mm, length 19-20mm or equivalent	Piece	10
31	Diameter 3.0mm, length 23-24mm or equivalent	Piece	12
32	Diameter 3.0mm, length 27-28mm or equivalent	Piece	12
33	Diameter 3.0mm, length 31-32mm or equivalent	Piece	12
34	Diameter 3.0mm, length 37-38mm or equivalent	Piece	10
35	Diameter 3.0mm, length 47-48mm or equivalent	Piece	7
36	Diameter 3.5mm, length 7-8mm or equivalent	Piece	2
37	Diameter 3.5mm, length 11-12mm or equivalent	Piece	5
38	Diameter 3.5mm, length 15-16mm or equivalent	Piece	8
39	Diameter 3.5mm, length 19-20mm or equivalent	Piece	9
40	Diameter 3.5mm, length 23-24mm or equivalent	Piece	10
41	Diameter 3.5mm, length 27-28mm or equivalent	Piece	10
42	Diameter 3.5mm, length 31-32mm or equivalent	Piece	10
43	Diameter 3.5mm, length 37-38mm or equivalent	Piece	10
44	Diameter 3.5mm, length 47-48mm or equivalent	Piece	7
45	Diameter 4.0mm, length 07-08mm or equivalent	Piece	2
46	Diameter 4.0mm, length 11-12mm or equivalent	Piece	5
47	Diameter 4.0mm, length 15-16mm or equivalent	Piece	3
48	Diameter 4.0mm, length 19-20mm or equivalent	Piece	7
49	Diameter 4.0mm, length 23-24mm or equivalent	Piece	7
50	Diameter 4.0mm, length 27-28mm or equivalent	Piece	7
51	Diameter 4.0mm, length 31-32mm or equivalent	Piece	7
52	Diameter 4.0mm, length 37-38mm or equivalent	Piece	5
53	Diameter 4.0mm, length 47-48mm or equivalent	Piece	4
54	Diameter 4.5mm, length 11-12mm or equivalent	Piece	3
55	Diameter 4.5mm, length 15-16mm or equivalent	Piece	4

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56	Diameter 4.5mm, length 19-20mm or equivalent	Piece	5
57	Diameter 4.5mm, length 23-24mm or equivalent	Piece	5
58	Diameter 4.5mm, length 27-28mm or equivalent	Piece	5
59	Diameter 4.5mm, length 31-32mm or equivalent	Piece	3
60	Diameter 5.0mm, length 11-12mm or equivalent	Piece	2
61	Diameter 5.0mm, length 15-16mm or equivalent	Piece	3
62	Diameter 5.0mm, length 19-20mm or equivalent	Piece	3
63	Diameter 5.0mm, length 23-24mm or equivalent	Piece	3
64	Diameter 5.0mm, length 27-28mm or equivalent	Piece	2
65	Diameter 5.0mm, length 31-32mm or equivalent	Piece	1

Duration of the Framework Agreement: **2 years (24 months) from signing.**

QSUT will sign a contract based on its needs every 4 months. With the exception of this definition, the contracting authority can sign a contract for any unforeseen need of medical supplies at any time necessary.

- **Time of Delivery (24 months):**

15% of the goods for each medical material must be delivered within 20 days after signing of the contract; Exceptionally, The CA determines the items, the quantity of which will be delivered in total within 20 days

The rest according to the requirements of the Cardiac Surgery Service and the Directorate of Pharmaceutical Service.

Appendix 13

[Appendix to be completed by the Contracting Authority]

STANDARD NOTIFICATION TO THE DISQUALIFIED BIDDER ⁴

[Place and date]

[Name and address of the contracting authority]

[Address of bidder]

Dear Sir/Madame <Contact name>

Thank you for participating in the above-mentioned public procurement procedure. The procedure was conducted in accordance with the Law “On Public Procurement”, no. 9643, dated 20.11.2006, “On PP Law”.

Your bid was carefully evaluated in accordance with the conditions and requirements established in the procurement notification and in the bid dossier. We regret to inform you that you were [disqualified] [eliminated because the bid submitted by you was rejected due to the following reason(s):

If you think that the Contracting Authority has violated the PPL or RPP during the public procurement procedure, then you have the right to initiate a review procedure as provided for in Chapter VII of the PPL.

Although we could not use your services in this case, I believe that you will continue to be interested in our procurement initiatives.

With respect

<Name>

⁴ This notification should be used in the case of procurement procedures to be developed in a written form

Appendix 14

[Appendix to be completed by the Contracting Authority]

AWARD NOTIFICATION FORM

[Date]

To: *[Name and address of the awarded bidder]*

* * *

Procurement procedure

Number of procedure/lot reference:

Short description of the contract: *[Quantities or purpose and duration of contract]*

Previous publications (if applicable): Public Notices Bulletin *[Date]* *[Number]*

Selection criteria for the winner: lowest price ☐ the most economically advantageous bid ☐

We hereby inform that the following bidders have participated in this procedure with these respective offered values:

1. _____

<i>Company's full name</i>	<i>NUIS number</i>
Value	
_____ <i>(Expressed in figures and words)</i>	

2. _____

<i>Company's full name</i>	<i>NUIS number</i>
Value	
_____ <i>(Expressed in figures and words)</i>	

Etc. _____

The following bidders have been disqualified:

1. _____

<i>Company's full name</i>	<i>NUIS number</i>
----------------------------	--------------------

Standard Tender Documents

2. _____

Company's full name

NUIS number

Respectively for the following reasons:

* * *

Referring to the above-mentioned procedure, we inform *[name and address of awarded bidder]* that the submitted bid, of a total value of _____ *[respective amount expressed in words and figures]*/ total points received *[_____]* has been identified as the successful bid.

Consequently, you are kindly asked to submit to *[name and address of the contracting authority and the contact reference]* the contract insurance, as provided with the bid documents, within _____ days from the receiving/ notification receipt.

If you don't comply with this request, or you withdraw from contract signing, your bid insurance shall be forfeited and the contract shall be awarded to the next bidder in the final classification, whose bid has been submitted with a total value of *[respective value expressed in words and figures]*, as provided for by article 58 of the Law for Public Procurements no. 9643 dated 20.11.2006, as amended.

Classification notification is made on _____

Complaints: yes or no _____

(if yes) has been answered on _____

* * *

[Head of the Contracting Authority]

Appendix 15

[Appendix to be completed by the Contracting Authority in the case of the framework agreement]

**NOTIFICATION FORM OF SUCCESSFUL ECONOMIC OPERATORS IN THE
FRAMEWORK AGREEMENT**

[Date]

To: [Name and address of the successful economic operators]

1. _____
2. _____
3. _____

* * *

Procurement procedure:

Number of procedure/lot reference:

Short description of the contract : [amount , scope , length of contract , etc.]

Previous publications (if applicable) : Public Notice Bulletin [Date] [Number]

Selection criteria for the winner: lowest price ☐ the most economically advantageous bid ☐

You are hereby informed that in these proceeding there have participated the following economic operators with the unit price multiplier provided/ the respective values as below:

1. _____	_____
<i>Company's full name</i>	<i>NUIS number</i>

Total of the unit prices for offered units / value

_____ (Expressed in figures and words)

2. _____	_____
<i>Company's full name</i>	<i>NUIS number</i>

Total of the unit prices for offered units / value

_____ (Expressed in figures and words)

Ect. _____

The following Economic operators have been disqualified:

1. _____	_____
<i>Company's full name</i>	<i>NUIS number</i>

2. _____	_____
<i>Company's full name</i>	<i>NUIS number</i>

Especially for the following reasons:

Standard Tender Documents

* * *

Referring to the above procedure, you are hereby informed that the following economic operators have been identified as successful:

1. _____
Company's full name *NUIS number*

Total of the unit prices for offered units / Value _____/
(Expressed in figures and words)

Total Points Received _____

2. _____
Company's full name *NUIS number*

Total of the unit prices for offered units /Value _____/
(Expressed in figures and words)

Total Points Received _____

Ect. _____

Consequently, you are requested to submit to [*name and address of the contracting authority and contact reference*] within _____ days from the date of receipt / notification of this notice to conclude the draft agreement.

Notice of Classification is made on _____

Complaints: yes or no _____
(if any) has been answered on _____

[Head of Contracting Authority]

Appendix 16

GENERAL CONDITIONS

Goods - Open Bid

Article 1: Purpose

- 1.1 The General Conditions of the Contract (GCC) shall apply to the supply of goods, procured with open procedure.
- 1.2 The Law of the Republic of Albania ‘On Public Procurement’ provides that the provisions of the Civil Albanian Code shall apply to the contracts of public procurement. Some provisions of this Code are expressed in the GCC as well, in order to increase the level of transparency in the contractual conditions. However, quoting some provision in this part, does not deny in any way the application of the other provisions of the Civil Code for this contract.
- 1.3 Similarly, some provisions of the Law on Public Procurement are expressed again in the GCC, in order to increase transparency in the law which regulates public procurement. However, the quoting of some provisions in this part, does not deny the application of other provisions of the Law on Public Procurement, regarding the parties’ rights, duties and obligations.
- 1.4 The GCC shall apply to the extent they do not leave behind the conditions or provisions, foreseen in other parts of the contract.
- 1.5 The contractual conditions comprise also the Specific Conditions of the Contract (SCC). Where there is a conflict between the GCC and the SCC, the SCC shall prevail over the GCC.

Article 2: Definitions

- 2.1 “Contract” means the written agreement between the Contracting Authority and the Contractor, which comprises the Bid Documents, including GCC and SCC, all attachments and completed forms, which are referred in each document.
- 2.2 “Contract Price” means the price to be paid to the Contractor, in accordance with the contract for the complete and precise implementation of his contractual obligations.
- 2.3 “Incoterms” means the international trade terms, as rules for the interpretation of trade terms determining the distribution of functions, costs, and risks related to the transfer of Goods from the Contractor to the Contracting Authority.
- 2.4 “Delivery” means all activities and actions for the receipt of Goods at the place of delivery, as specified in the contract, such as packaging, transport, security, tariffs, customs procedure, loading and unloading services, installation, collection, inspection of actions and the monitoring of the overall activity.

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- 2.5 “Contracting Authority” means the Contracting Authority which is a party to this Contract, and which contracts the Goods of this contract. This term shall have the same meaning with the one defined in the law.
- 2.6 “Contractor” means the natural or legal person, which is party in this contract and, in accordance with the provisions of this contract, is the one who supplies the Goods.
- 2.7 “Party (-ies)” mean the signatories of the contract.
- 2.8 “Goods” means all unprocessed materials, products, machineries and equipment, solid, liquid or gas objects.
- 2.9 “Related services” means all secondary services or unpredicted services for the supply of Goods, such as transport, installation, maintenance, training, supporting services or similar obligations related to the supply of Goods.
- 2.10 “Scope of Contract” means all the Goods and the Related Services that the contractor shall provide, complying with the conditions of the contract.
- 2.11 “Technical Standards” means the approved specification by a specialized body of standardization for ongoing or repeated application. These standards are used as rules, regulations or definitions of the characteristics, in order to insure that the materials and related services meet the objective.

Article 3: Drafting of Contract

- 3.1 The notification of the awarded bid shall serve for the preparation of the contract between the parties, which shall be signed within the time limit set in the Bid Documents.
- 3.2 The existence of the contract shall be confirmed with the signature of the contract document, embodying all the agreements between the parties.

Article 4: Corrupt Practices, Conflict of Interest and Inspection of Reports

- 4.1 The Contracting Authority can request the Court to declare as illegal the contract, if he discovers that the Contractor has carried out corruptive acts. Corruptive acts include all acts described in Article 26 of the Law on Public Procurement.
- 4.2 The Contractor shall not have relations (current or past ones) with any of the consultants or any other entity, which participated in the preparation of the Bid Documents for the named procurement.
- 4.3 The Contractor shall allow the Contracting Authority to inspect the accounts and the registers, which are related to the Contract implementation, or to control them through audits appointed by the Contracting Authority.

Article 5: Confidential Information

- 5.1 The Contractor and the Contracting Authority shall keep as confidential all the documents, data and other information provided by the other party, in relation with

the Contract.

- 5.2 The Contractor can give to a Sub-contractor such documents, data or other information taken by the Contracting Authority to the extent required by the Sub-contractor to carry out its part of the work, in accordance with the Contract. In this case, the Contractor shall include in his contract with the Sub-contractor a provision, which deals with confidentiality, as mentioned above in Paragraph 5.1.

Article 6: Intellectual Property

- 6.1 Except when otherwise provided in the Contract, all the rights of intellectual property, provided by the Contractor during the implementation of the Contract, shall belong to the Contracting Authority, which may use them, as it deems appropriate.
- 6.2 Except when otherwise provided in the Contract, the Contractor, after the end of the Contract, shall submit to the Contracting Authority all reports and other data such as maps, diagrams, specifications, plans, accounts, statistics and supporting registers or materials gathered or prepared by the Contractor during the implementation of the Contract. The Contractor can keep copies of these documents and data, but he shall not use them for purposes, which are not related to the Contract, without a preliminary written permission of the Contracting Authority.
- 6.3 The Contractor shall insure the Contracting Authority against the lack of responsibility for infringement of rights related to the intellectual property, which may arise from the production or distribution of Goods, in accordance with the Contract.
- 6.4 If there is any claim or suit against the Contracting Authority, regarding any infringement of the intellectual property, caused during the implementation of the Contract or during the use of Goods, supplied in accordance with the Contract, the Contractor shall provide to the Contracting Authority all the evidence and the necessary information, which is related to the named suit or claim.

Article 7: Goods' Origin

- 7.1 There is no restriction for the nationality of the origin of materials, except those which may be determined in any of the Resolutions of the General Assembly of the United Nations.
- 7.2 The Contractor may be obliged to verify the origin of materials.
- 7.3 For purposes of verification, "origin" implies the place where the materials were found, manufactured or raised. It is said that a certain material has been manufactured when, after production, processing, or gathering of components, the result is a new product, recognized in the market, which is very different from the basic characteristics or from the use and scope of its components.
- 7.4 The origin of materials differs from the nationality of the Contractor or Sub-contractor, who supplies the materials.

Article 8: Supply Scope and Goods' Compliance with the Specifications

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- 8.1 The Contractor shall deliver The Goods with the quality, quantity and type specified in the contract, as well as placed and packed as provided in the contract.
- 8.2 The Goods are not in accordance with the contract if those are not qualified to the special use provided in the contract. When not possible to determine such element, it is deemed that The Goods are not in conformity with the contract if those are not suitable to the use to which usually serve other same objects.
- 8.3 If the vending is based on a model or sample, the Supplier (Contractor) shall deliver the objects that have the same qualities of the model or sample.

Article 9: Goods' Compliance with the Technical Standards

- 9.1 The Goods supplied as per contract shall be conform the codes and Technical Standards provided in the technical specifications. If during the execution of the contract there are amendments to the respective codes or Technical Standards, these amendments will be applied only after approval by the Contracting Authority.
- 9.2 Unless otherwise provided by any other provision of the contract, if there is not defined any respective Technical Standard in the Technical Specifications, The Goods shall be in accordance with the current international Technical Standards. If the international Technical Standards do not exist, The Goods shall be in accordance with the Albanian respective Technical Standards.
- 9.3 The Contractor shall not be responsible for mistakes given by the Contracting Authority in diagrams, data, designs or other aspects of the technical specifications, except the case when the mistake is obvious and the Contractor shall have notified of such mistake and advise the Contracting Authority about it.
- 9.4 The Supplier (Contractor) is not responsible for Goods defects on which the Contracting Authority was informed in the moment of the contract signing or was not informed because of its fault, except when the defects have to do with the quality of the Goods specified according to the contract or the representation of advertisement of the supplier (Contractor).

Article 10: Spare Parts

- 10.1 If stipulated in the contract, the Contractor shall include with the Commodities Commitment a quantity of spare parts, in accordance with the technical specifications and any relevant provision of the contract.
- 10.2 Except as otherwise provided, the exchange parts shall be delivered together with the Goods.
- 10.3 The Contractor shall guarantee the availability of spare parts for a period specified in his offer and equal to the lifetime of the Goods.
- 10.4 In the case of a termination decision on the production of spare parts, the Contractor shall notify the Contracting Authority within a reasonable time to allow him / her to procure sufficient quantities for subsequent use.

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- 10.5 Upon termination of production of spare parts, the Contractor shall give the Contractor, free of charge, any Equipment, Tools, Design of spare parts used in the manufacture and maintenance of the Goods if he so requests.

Article 11: Packaging

- 11.1 The Contractor shall deliver the Goods, in the manner and packaging form, as specified in the Contract.
- 11.2 Unless otherwise provided in another article of the contract, it may be assumed that Goods were not delivered in the manner and packaging form, as specified in the Contract, if this manner or form was different from the usual manner used for items of the same type or if the usual manner is no longer available, in a manner appropriate for the maintenance and protection of Goods.

Article 12: Tests and Inspections

- 12.1 The Contractor shall perform all tests and inspections, requested by the provisions of the Contract. The cost of these tests and inspections shall be entirely financed by the Contractor, within the price of the Contract.
- 12.2 At its own expense, the Contracting Authority is entitled to follow the tests and/or inspections.
- 12.3 The Contracting Authority may ask to the Contractor to make additional tests and inspections, which were not foreseen in the Contract, but which have been judged as necessary to verify that the Goods are in conformity with the specifications and with the Contract's terms and conditions. The Contracting Authority will be charged with the cost of these tests. In addition, if these tests obstruct the work progress of the Contractor, the Contracting Authority shall agree to change the Delivery Schedule.
- 12.4 The Contracting Authority shall reject any Goods, which do not pass the test and/or inspection, or is not in conformity with the Technical Specifications and the conditions, set for the execution of the Contract.
- 12.5 Neither the performance of tests, nor the inspection of the Goods, shall free the Contractor from any guarantee or other obligation, in accordance with the Contract.

Article 13: Delivery conditions

- 13.1 The contractor is obligated to perform all the activities and acts of delivering, except when the Contractor is specifically disqualified from such an activity or act by a provision of the contract. If any Incoterm is used to describe the parties' obligations, the term shall have the meaning given by the last publication of the *Incoterms, published by the International Chamber of Commerce*.
- 13.2 The place of Goods delivery shall be as specified in the contract.
- 13.3 Delivery time of Goods and final date of the Related Services shall be as specified in the contract.
- 13.4 Delivery of Goods shall be done during working hours, except when otherwise provided in the contract.

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13.5 The contractor is obligated to give to the Contracting Authority a reasonable notification on the Goods delivery before their departure.

Article 14 Transport of Goods

14.1 The contractor is obligated to provide loading and transportation of the as required, in order to accomplish the terms and conditions specified in the contract.

14.2 If the contracting authority is obligated to receive the Goods by a transportation vehicle or transportation agency, the contractor shall give prior reasonable notification of the transportation and shall give to the contracting authority all the necessary documents to receive the Goods.

14.3 If the supplier [Contractor] is obliged to deliver the goods in the transportation vehicle in a place specified in the contract, the risk of loss is transferred to the contracting authority only when the goods are delivered in the transportation vehicle in the specified place. The fact the supplier [Contractor] is authorized to keep the representative documents of the goods does not influence the risk transfer.

Article 15: Insurance

15.1 Unless otherwise provided with a different provision of the contract, the Contractor shall insure that the Goods to be delivered following the Contract are completely secured against loss or damage during transport, depositing or delivery.

Article 16: Examination and Acceptance of Goods

16.1 Prior to accepting, the Contracting Authority has the right to examine, inspect and test the Goods. This activity shall be carried out immediately following the Goods delivery. The Contractor has the right to participate in this activity and to examine the activity reports, drafted by the Contractor Authority or its agents.

16.2 The Contracting Authority shall accept or refuse the Goods immediately after their delivery, and shall provide the Contractor with a written notification regarding its actions to accept or refuse the Goods.

Article 17: Guarantees

17.1 The Contractor guarantees that the Goods are new, unused and belong to the last models, and that they embody all latest updates and improvements in terms of designs, materials, except when otherwise provided in the Contract.

17.2 The Contractor is responsible for any defects or unfitness that existed at the moment when the risk passed to the Contracting Authority, even when the defect appears after this moment.

17.3 The Contractor is responsible even for the unfitness that is verified after the moment indicated in the above paragraph and that comes from the non-fulfillment of any obligation, including the warranty that the Goods will be suitable for their common or specific usage for a certain period of time, or that will retain its quality and specified characteristics

17.4 .Except otherwise provided by another provision of the contract or by law, the

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Contracting Authority loses his right to challenge things for defects, if he does not notify the Contractor, within ten days of the discovery, specifying their nature.

17.5 The Contracting Authority shall provide the Contractor all the reasonable opportunities for the Contractor to inspect such defects.

17.6 Upon receipt of such notification, the Contractor shall promptly repair or replace the defective Goods or parts thereof at no cost to the Contracting Authority.

17.7 If after receiving notification, the Contractor fails to remedy the defect within a reasonable period, the Contracting Authority may proceed, at the Contractor's expense, to take such remedial action as may be necessary.

17.8 In any case, the Contracting Authority loses his right to challenge things for defects if he does not exercise his right within two years from the date of delivery of such things to him, provided such term is not contrary with the duration of a contractual warranty.

17.9 The Contractor cannot take advantage of the rules provided in herein if the defects deal with facts within his knowledge or that could not have been unknown to him and these were not brought to the attention of the Contracting Authority.

Article 18: Contract Price

18.1 The contract price shall be the price submitted with the Contractor's bid and accepted by the Contracting Authority.

18.2 Except as otherwise provided in the contract, the contract price includes the costs and charges, including taxes and customs duties related to the delivery of the Goods, transportation charges, security, installation, testing, loading, unloading, instructions, manuals and documents in the language specified and necessary for the use, maintenance, and repairs of the Goods. The value of taxes and fees should be determined according to the relevant legislation, in force 28 days before the opening of the bids.

Article 19: Payment deadline

19.1 The contract price, including any advance payment, shall be paid in time as specified in the contract.

19.2 Unless otherwise provided in the contract, payment shall be made in Albanian currency. The exchange rate of different currencies will be the Bank of Albania course fixed on the day of sending for publication of the contract notice.

19.3 Except as otherwise provided in the contract, the Contractor's request for payment shall be made to the Contracting Authority in writing. For each request, the Contractor must submit the original and the copy together with a list of items describing the Goods Submitted and the services rendered.

19.4 Except as otherwise provided in the contract, payment for Goods shall be made within 30 calendar days of receipt of the Goods or from the day of receipt of the payment claim whichever is the later.

19.5 The payment date shall be the day that funds are levied from the Account of the Contracting Authority.

Article 20: Delay in Payment

In the case of verification of delays in making payments by the Contracting Authority, although the Contractor has fulfilled all its obligations in accordance with the terms of the contract, the arrears and the relevant interest charges shall be made in accordance with the provisions of Law no. 48/2014 "On late payments in contractual and commercial liabilities".

Article 21: Amendment of the Law and Rules

21.1 If, after the date of contract signing, any law, regulation, directive or procedure with the effect of the law in the Republic of Albania comes into force, is issued or amends and affects the conditions, including the date of delivery, or the contract price, the terms and conditions and the price of the Contract shall be regulated at the extent the Contractor has been affected in meeting his obligations, in accordance with the Contract.

Article 22: Force majeure

22.1 The Contractor shall not be held responsible for the loss of the Contract Security, for liquidated damages or cancellation for non-fulfillment, if, and to the extent the delay or any other failure in carrying out his obligations in accordance with the contract, is the result of a force majeure.

22.2 For the purposes of this article, "Force Majeure" means an unforeseen happening or event outside the control of the Contractor regarding fault or negligence. These events can include, but are not limited to the actions of the Contracting Authority, in its sovereign or contractual capacities, war or revolutions, fire, flood, earthquake, epidemics, quarantine pressure and transit embargo.

22.3 If an event of a force Majeure occurs, the Contractor shall immediately notify the Contracting Authority. Except when the Contracting Authority gives different directives, the Contractor shall continue implementing all its obligations, in accordance with the Contract, at a reasonable extent, and shall require all reasonable means for this implementation, which are not obstructed by any Force Majeure.

Article 23: Delays in Implementation and Extension of Time Limits

23.1 Except when otherwise provided, the Contractor shall start to implement the Contract, immediately following its signing.

23.2 Except when the Contracting Authority agrees for an extension of the Contract time limits, the Contracting Authority has the right to liquidate the damages for the delay in implementation, if the Contractor fails to deliver the Goods within the complete execution period, as specified in the Contract.

23.4 The Contracting Authority can deduct the value of liquidated damages from the amount to be paid to the Contractor. In this case, the Contracting Authority shall give to

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the Contractor a written notification on the value and reason of such deduction.

23.5 The Contracting Authority shall agree on an extension of the time limits, in cases of force Majeure.

23.6 The Contracting Authority can agree on an extension of the time limits, even in other circumstances, if it is in the public interest. If the Contractor encounters conditions, which obstruct the implementation in time, the Contractor shall promptly notify in writing the Contracting Authority regarding the delay, the causes and the date proposed for the delivery or the conclusion. The Contracting Authority shall evaluate the request. If the Contracting Authority agrees with the delay, the extension shall entry into force with a written amendment of the Contract, signed by the Contracting Authority and the Contractor.

Article 24: Damage Liquidation related to delays in Delivery

24.1 Liquidated damages for delayed goods delivery shall be calculated with the following daily fees:

a) For contracts with an implementing period, not more than 6 months, the daily fee shall be 4/1000 of the corresponding remaining value, from the total price of the Contract, but not less than 25% of the contract value.

b) For contracts with an implementing period, not more than 12 months, the daily fee shall be 2/1000 of the corresponding remaining value, from the total price of the Contract, but not less than 25% of the contract value.

c) For contracts with an implementing period more than 12 months, the daily fee shall be 1/1000 of the corresponding remaining value, from the total price of the Contract, but not less than 25% of the contract value

Article 25: Negotiations and Amendments

25.1 The parties shall not negotiate for modifications or amendments in any of the elements of the Contract, which would considerably change the conditions constituting the basis for the selection of the Contractor.

25.2 No amendment or any other contract variation shall be valid without being in written form, dated and referring expressly to the Contract, or if it is not signed by an authorized representative of the Contractor and of the Contracting Authority.

25.3 Any waiving of rights, powers or corrections of the parties, in accordance with the Contract, shall be done in writing, shall have a date and shall be signed by an authorized representative of the party, which withdraws from such right, and shall specify the right and the extent of it.

Article 26: Modification of Order

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- 26.1 The Contracting Authority reserves the right to order additional goods or services, but only in accordance and in circumstances provided with the PPL and provided that the increase of cost shall not exceed 20% of the total price of the Contract.

Article 27: Cancellation because of Non-Fulfillment

The Contracting Authority may cancel the Contract, completely or partly, if:

- a) The Contractor fails to complete the delivery of Goods within the specified time limit in the Contract, or within the granted extension; or,
- b) The Contractor fails to fulfill any other obligation of the Contract.

27.2 The Contracting Authority shall give to the Contractor a written notification for the cancellation for non-fulfillment and grant to the Contractor 15 days to adjust the non-fulfillment, except when such decision for cancellation was taken for corrupted and illegal actions, in which case, the cancellation shall be immediate.

Article 28: Cancellation because of Bankruptcy

- 28.1 The Contracting Authority may cancel the Contract at any time, if the Contractor is bankrupt or becomes unable to pay

28.2 The Contracting Authority shall give to the Contractor a written notification regarding the cancellation.

Article 29: Cancellation in the public interest

- 29.1 The Contracting Authority may cancel the Contract at any time, if it deems that this decision shall be taken, in order to better serve the public interest.

- 29.2 The Contracting Authority shall give a written notification to the Contractor, regarding this cancellation.

- 29.3 The Contracting Authority shall pay the Contractor for all accepted Goods and related Services, which were delivered prior to cancellation and shall pay the Contractor for the damages caused by the partial delivery of Goods and Related Services. While calculating the value of damages, the Contractor shall be required to undertake all necessary actions, in order to minimize the damages.

Article 30: Sub-Contracting

- 30.1 Sub-contracting shall be valid only if it exists in the form of a written agreement, through which the Contractor accredits a part of the contract's obligations to a third party.

- 30.2 The Contractor shall not sub-contract without a prior written approval of the Contracting Authority and not more than 40% of the contract value. The Contractor shall notify the Contracting Authority regarding the Contract elements, which have been sub-contracted and regarding the documentation that proves the capability of the Sub-contractor. Within 5 days from the receipt of notification, the Contracting Authority shall notify the Contractor about his decision, expressing the reasons whether he approves it or not.

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30.3 Every Sub-contractor shall have the right to participate in public procurement, in accordance with the Law on Public Procurement. The Contracting Authority may foresee direct payments for the sub-contractor in return of goods that he shall supply.

30.4 The Contractor remains fully responsible for the contract implementation, regardless the subcontractor's performance.

Article 31: Transfer of Rights

31.1 The Contractor shall not completely or partly, transfer his obligations according to the Contract, except when preliminary decision of the Procuring Entity is taken.

Article 32: Contract Insurance

32.1 Within 30 days from the receipt of the notification for the contract award, the Contractor shall give to the Contracting Authority the guarantee of a Contract Insurance at the acceptable amount and form, as specified in the Contract. Failure in providing a Contract Insurance in the required form and amount, within 30 days, shall result in the cancellation of the Contract and in the forfeit of the Contractor's Bid Security.

32.2 The amount of the Contract Insurance shall be paid to the Contracting Authority as a compensation for any loss, resulting from failure of the Contractor in meeting his obligations, in accordance with the Contract.

32.3 The Contract Insurance shall be returned to the Contractor not later than 30 days after the date of Goods acceptance. However, 5 (five) percent of the Insurance shall be kept, until a satisfactory fulfillment of the contractual obligations.

Article 33: Legal Grounds

33.1 The Contract shall be governed and interpreted according to the Laws of the Republic of Albania.

Article 34: Settlement of disputes

34.1 The Contracting Authority and the Contractor shall make all attempts to resolve their conflicts or disputes, through direct negotiations.

34.2 If the parties fail to resolve the disputes or the conflict, these shall be resolved following the Contract and the legal procedures in force, in accordance with the Legislation of the Republic of Albania.

Article 35: Representation of the Parties

35.1 Each party shall nominate in writing a person or appoint an organizational structure, which shall be responsible, in behalf of the party, for the receipt of communications and for the representation of the party in issues related to the Contract execution.

35.2 Each party shall immediately notify the other party, regarding any change in the nomination of the party's representative. If one of the parties fails to notify, it shall be charged for all damages, caused by the failure to give a proper notification.

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35.2 The parties may nominate persons or additional organizational units to represent them in particular actions and activities. In any case, a written notification shall be provided and it shall determine the extent of the representative's authority.

Article 36: Notifications

36.1 In accordance with the Contract, all notifications from any of the parties to the other, shall be in writing, and sent at the address specified in the Contract

36.2 The notification enters into force, as soon as it is delivered.

Article 37: Calculation of Time Limits

37.1 All references to days shall be calendar ones, except when otherwise provided.

Appendix 17

[*Appendix to be completed by the Contracting Authority*]

SPECIFIC CONDITIONS

Goods – Open Procedure

The following Special Conditions of the Contract shall be complementary to the General Conditions of the Contract. In the case of discrepancies, the provisions herein shall prevail over the provisions in the General Conditions.

Article 1: Definitions

1.1 The Contracting Authority is _____

1.2 The Contractor is _____

Article 2: Contract Security

2.1 The Contractor shall provide the Contract Security, at the amount of *10% of the bid value*, in order to assure the execution of his obligations, in accordance with the Contract.

2.2 Contract Security shall be promptly issued or returned to the Contractor, according _____ to _____ the following form:

Article 3: Start of Implementation

3.1 The contract implementation shall start on _____. If the date is not defined, the implementation shall start on the date the Contractor signs the Contract Form.

Article 4: Inspections and tests

Standard Tender Documents

- 4.1 Inspections and tests before acceptance of goods will be made: _____

Article 5: Conditions of Delivery

- 5.1 The delivery conditions, the dates and places of the delivery of goods and of spare parts will be accomplished according to the Delivery Schedule stipulated in this contract..
- 5.2 The contractor shall notify the CA _____ days before each delivery of goods.
- 5.3 Notification of delivery shall be made in writing, by fax, mail, e-mail etc. to: _____

- 5.4 If the Contracting Authority takes the goods from a third party, the delivery notification shall include the list of necessary documents for receiving goods and shall indicate the documents will be given to the Contracting Authority.
- 5.5 If the Contracting Authority takes the goods from a third party, the Contractor shall consign all the necessary documents for receiving goods to: _____

Article 6: Payment Conditions

- 6.1 Payment of goods shall be made within _____ days from date of acceptance the goods or from date taking the payment request in written, regardless the day of coming. If it is not specified, the time period will be 30 days.
- 6.2 The payment will be made in _____. If it is left unfilled, the payment will be made in Albanian currency.

Article 7. Prepayment

- 7.1 The prepayment percentage will be _____. If not specified, the Contractor will not receive a pre-payment.
- 7.2 If a prepayment is promised, the advance will be paid within _____ days from the receipt of the contract security.
- 7.3 If a prepayment is made, the amount shall be deducted from the payment to be made to the Contractor under the following formula: _____

Article 8. Related Services

- 8.1 The following special conditions will be executed for making the payment of related Services.

Article 9. Reduction of the contract insurance

9.1 If a periodic reduction of the contract insurance is foreseen, it is performed as follows:

If it is not filled, the insurance remains unchanged.

Appendix 18

[*Appendix to be completed by the Contracting Authority*]

FORM OF SIGNED CONTRACT NOTIFICATION

Section 1 **Contracting Authority**

1.1 Name and address of Contracting Authority

Name _____

Address _____

Tel/Fax _____

E-mail _____

Website _____

I.2 Type of the Contracting Authority:

Central institution	Independent institution
<input type="checkbox"/>	<input type="checkbox"/>
Local Government Unit	Other
<input type="checkbox"/>	<input type="checkbox"/>

Section 2. The object of Contract

2.1 Reference number of procedure / lot

2.2 Type of “Public Contracts for Goods”

Purchase	Rent	Leasing	Purchase in installments	A combination of these
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2.3 Contract under the Framework Agreement

Yes ☐ No ☐

If Yes, type of Framework Agreement

With one Economic Operator ☐

With some economic operators ☐

All conditions are set Yes ☐ No ☐

2.4 Short description of contract

1. Limit fund _____
—
2. Source of financing _____
3. Scope of contract/ framework agreement _____

2. 5 Duration of the contract or completion deadline:

Duration in months □□□ or days □□□□

or

Starting from □□/□□/□□□□ and completion on □□/□□/□□□□

2.6 Division into LOTS:

Yes ☐ No ☐

If yes, the number of LOTS: □□

Standard Tender Documents

2.7 Options:

Number of possible renewals (*if any*): ☐☐

or: from ☐☐ to ☐☐☐☐

2.8 Contract with subcontracting:

Yes ☐ No ☐

Section 3. Procedure

3.1 Type of procedure: Open

3.2 Winner selection criteria:

A) the lowest price ☐

or

B) the most economically advantageous bid ☐

As per importance: Price ☐☐ points ☐

ect. ☐☐ point

3.3 Number of submitted bids: ☐☐☐☐ ☐☐

Number of regular bids: ☐☐ ☐☐

3.4. During the procurement process in the field of Information and Communication Technology (ICT) there have been used the standards prepared by the National Agency for Information Society:

Yes ☐ No ☐

3.5. During the procurement process in the field of Information and Communication Technology (ICT), when standards are not applicable, prior approval is obtained by the National Agency for Information Society.

Yes ☐ No ☐

Section 4 Information about the contract

Standard Tender Documents

4.1 Contract number: _____ **Contract date**
□□/□□/□□□□

4.2 Name and address of the contractor

Name

Address

Tel/Fax

E-mail

Website

4.2.1 Name and address of the subcontractor/s

Name

Address

Tel/Fax

E-mail

Website

4.3 Total final value of the contract *(including lots, options and subcontracting):*

Value _____ Currency _____
(excl. VAT)

Value _____ Currency _____
(incl. VAT)

4.3.1 Total value of subcontracting: _____

Value _____ Currency _____
(excl. VAT)

Standard Tender Documents

Value _____
(incl. VAT) Currency _____

4.4 Additional Information

Date of delivery of this notification □□/□□/□□□□

Appendix 18/1

[Appendix to be completed by the Contracting Authority for publication in the Public
Notifications Bulletin]

1. Name and address of Contracting Authority

Name _____
Address _____
Tel/Fax _____
E-mail _____
Website _____

2. Type of procedure:

3. Object of the contract / framework agreement

4. The reference number of the procedure / lot

5. Limit Fund

Total final value of the contract (*including lots, options and subcontracting*):

Value _____
(incl. VAT) Currency _____

Value of subcontracting _____ *incl. VAT* Currency _____

Standard Tender Documents

7. Date of contract signing

7. Name and address of the contractor / subcontractor

Name

Address

NUIS number

Appendix 19

[Letterhead of the Bank / Insurance Company]

[*Appendix to be completed by the Economic Operator*]

CONTRACT INSURANCE FORM

[Date]

To: *[Name and address of the Contracting Authority]*

On behalf of: *[Name and address of the guaranteed bidder]*

* * *

Procurement procedure: [type of procedure]

Short description of the contract: *[subject]*

Publication (if applicable): Public Notifications Bulletin [Date] [Number]

* * *

With reference to the above-mentioned procedure and provided that *[name of the awarded bidder]* has been awarded the contract, we certify that *[name of the awarded bidder]* has made a deposit near the *[name and address of the bank / insurance company]* at the amount of *[currency and amount both in letters and numbers]* as a condition to secure the performance of the contract to be signed with *[name of contracting authority]*

Standard Tender Documents

We undertake to transfer to the account of [*name of the contracting authority*] the secured amount, within 15 (fifteen) days from your first written request, without asking for explanations, on condition that the request mentions the non-fulfillment of the obligations of the contract.

This Insurance is valid up to the complete execution of the contract.

[Representative of the bank / insurance company]

Appendix 20

COMPLAINT FORM SUBMITTED TO THE CONTRACTING AUTHORITY

Complaint to: Contracting Authority ☐

Section I *Complainant Identification*

The complainant can be a bidder or a potential bidder (e.g. individual, partnership, corporation, joint venture).

Complainant's full name (please type)

Address

City

State

Postal code/ Zip
Code

Telephone No. (including area code)

Fax No. (including area code)

E-mail

Name and title of authorized official filing the complaint (please type)

Standard Tender Documents

Signature of authorized official

Date (year/month/day)

Telephone No. (including area code)

Fax No. (including area code)

Section II. Information about the Procedure

1. Identification Number

*Fill the contract number provided in the contract notification or bid documents including the **type of procedure used** for the procurement in dispute (e.g. Request for Proposal [RFP], Open procedure [OP], Restricted procedure [RP], Negotiated Procedure [NP], Consultative Service [CS], Designing Contest [DC]).*

2. Contracting Authority

Name of the Contracting Authority administering the procurement process.

3. Estimated value of the Procurement

Estimate of the contract value (amount in figures and words)

4. Subject of the Contract

Short description of works/ goods/ services being purchased. .

5. Deadline for Bid Submission

Deadline for Bid Submission

6. Contract Award Date

Date (year/month/day)

Date (year/month/day) if applicable

Section III. Description of the complaint

1. Complaint Legal Grounds

(Describe the legal infringement with regard to decisions, deeds, documents etc)

2. Detailed statement of facts and arguments

Give a detailed statement of the facts and arguments that support your complaint. For each reason of your complaint specify the date when you were informed on the facts related with the reasons of your complaint. Also mention the relevant sections of the bid documents, if applicable. Use additional sheets if necessary.

3. List of Appendixes

*In order for a complaint to be considered filed, it shall be complete. Attach a legible copy of all documents that are relevant to your complaint and a list of all these documents. The documents would normally include **any notification published, all bid documents, with all amendments and attachments; your proposal**. Indicate which information, if any, is confidential. Explain why the information is confidential or provide either a version of the relevant documents with confidential parts removed and a summary of the contents.*

Send the completed procurement complaint form, all the necessary appendices and some additional copies, to the **Contracting Authority**

Note: Regarding the complaints to the Public Procurement Commission, please refer to the Complaint Form issued by this Institution

Fax No:

E-mail:

Signature and seal of the complainant

Appendix 21

**DRAFT OF THE FRAMEWORK AGREEMENT
(WHERE ALL TERMS ARE DEFINED)
FOR WORKS / GOODS / SERVICES**

[Use of this draft agreement is binding on all contracting authorities who will use the framework agreement]

No . __

DATED :

This Agreement is entered on [date] between [name and address of the Contracting Authority], hereinafter referred to as " the Contracting Authority " and [name and address of Contractor] represented by [representative] , hereinafter referred to as " Contractor " .

Contractor , through its bid, dated [date] agrees to supply the goods, as specified in the terms set out in:

- This Contract Form
- Declaration Form of Bid submitted by the Bidder
- Technical Specifications
- Form of Bid Price

All these documents are attached form an integral part of this Contract.

Article 1 Scope

Standard Tender Documents

1.1 The purpose of the framework agreement is to define the terms, including prices per unit and the rules for the delivery of the following goods / services / works.

[General description]

1.2 The framework agreement will be implemented by sending invitations for bids to economic operators, parties to the agreement. For example, wherever the Contracting Authority involved in this agreement, will purchase items under this framework agreement, he should send "invitation for bids " to the contractor, specifying the list of items to be supplied with their respective quantities.

1.3 Amounts provided herein are only for orientation purposes and do NOT oblige the Contracting Authority to acquire them. The Contracting Authority has the right to buy less or more quantities than those provided.

1.4 The Contractor shall not be entitled to compensation and will not be allowed to make changes to the unit prices, for example if the Contracting Authority decides to buy less or more quantities than those provided specified and / or if the Contracting Authority decides not to buy ANY of these quantities for some items.

1.5 Duration of the framework agreement:_____

Article 2 Price

2.1 The unit prices for work / goods / services are shown in the Form of the Bid Price.

2.2 Unit Prices shall be fixed and not subject to change for orders placed on this framework agreement.

Signatures and Dates

For the Contractor		For the Contracting Authority	
Name:		Name:	
Position:		Position:	
Signature:		Signature:	
Date:		Date:	
Seal:		Seal:	

Appendix 22

**DRAFT FRAMEWORK AGREEMENT
(WHERE NOT ALL THE TERMS ARE DEFINED)
FOR WORK / GOODS / SERVICES**

Name of the Contracting Authority,
And

Name of the Contractor

Agree as follows :

To sign the framework agreement for the object : < insert title > with identification number :
< *insert Procurement Number* >

Article 1 Scope

1.1 The object of this framework agreement is to establish the rules for contracts that will be connected via Mini - competition process only between economic operators who are party to this Framework Agreement .

1.2 This framework agreement is not a contract in itself but sets the conditions for the contracts that will be entered into, based on it.

1.3 The Contractor is only one of parties of the framework agreement.

Article 2 Liabilities of the Parties

- 2.1 The Contracting Authority, a party to this agreement, shall send to the Contractor an " Invitation to Bid " whenever there is a need for work / goods / services .
- 2.2 The Contractor is obliged to submit a bid whenever required by the Contracting Authority.

Article 3 Contracts in the implementation of the Framework Agreement

- 3.1 Contracts will be signed only after the Mini - competition process.

Article 4 Mini - competition process

- 4.1 The mini- competition process will be conducted with all economic operators, parties to the framework agreement, wherever there is a need for work / goods / services to the Contracting Authorities.
- 4.2 The Contracting Authority will re - open competition under the same conditions or other conditions set forth in the invitation for bids, as laid down in the tender documents.
- 4.3 Whenever there is a need for works / goods/ services, the Contracting Authority must prepare Invitations for Bids and send them to all economic operators, parties to the framework agreement. Evaluation of Bids will be based on the criteria set out in the Invitation to Bid.

Article 5 Duration of the framework agreement_____

Signatures and dates_____

For the Contractor		For the Contracting Authority	
Name:		Name:	
Position:		Position:	
Signature:		Signature:	
Date:		Date:	
Seal:		Seal:	

Standard Tender Documents

[*Appendix to be completed by the Contracting Authority*]

CANCELLATION NOTIFICATION FORM

1. Name and address of Contracting Authority

Name _____

Address _____

Tel/Fax _____

E-mail _____

Website _____

1. Type of procedure: _____

2. Reference Number: _____

3. Subject of the contract _____

4. Limit Fund _____

5. Reasons for Cancellation:

Based on Law no. 9643, dated 20.11.2006 "On Public Procurement" as amended, Article 24, point 1:

a) ;

b) ;

c) ;

ç) ;

d) ;

dh) ;

Ect. _____

**6. Additional
information** _____

Date of delivery of this notification _____