Date 10/07/2023

MINUTES- Type of the contract – Services

FOR THE ARGUMENTATION AND APPROVAL OF TECHNICAL SPECIFICATIONS AND QUALIFICATION CRITERIA

OBJECT: **Maintenance of large medical equipment of the manufacturer Philips/or equivalent, manufacturer Siemens/or equivalent, and manufacturer Toshiba/or equivalent" for 24 months", divided into lots (total 2).**

RELEVANT CODE IN THE COMMON PROCUREMENT VOCABULARY (CPV):

Maintenance and Repair Services: 50000000-5;

Various Repair and Maintenance Services: 50800000-3

LIMIT FUND: **(Expected Value of Contracts):** The limit fund of the Framework Agreement (Expected Value of Contracts): **155,150,265.3** (one hundred and fifty-five million one hundred and fifty thousand and two hundred and sixty-five point three) **ALL without VAT**,

The limit fund /expected value of contracts for all lots, converted to Euros according to the official rate of the Bank of Albania is: 1,485,544.48 Euros without VAT, and the sum of the prices (for lot 2) per unit calculated in euros is: 104,44 Euros without VAT.

Procedure/Lot reference number: Lot reference number: REF-74712-07-10-2023, Lot reference number:

Lot no.	*Designation of the Lot*	Reference
1.	-Lot 1 - Medical equipment manufacturer Philips/or equivalent:	**REF-74716-07-10-2023**
2.	-Lot 2 - Medical equipment manufacturer Siemens / or equivalent:	**REF-74718-07-10-2023**

Based on article 21, point 2, of Law no. 162/2020 "On public procurement", article 2, point 2/c and article 78, point 2, of DCM no. 285, dated 19.05.2021 "On the approval of public procurement rules", the contracting authority/entity "University Hospital Center "Mother Teresa" has drawn up the protocol for the argumentation and approval of the technical specifications and qualification criteria for the above-mentioned procedure, with the content as lower:

I. SPECIAL QUALIFICATION CRITERIA

(SAME FOR ALL LOTS)

1. **The bidder must submit**:

a. *The Bid Form, according to* ***Appendix 1*****;**

Argumentation: This criterion was established according to Article 29 of DCM no. 285, dated 19.05.2021 "On the Approval of Public Procurement Rules", in which it is provided that: 1. The economic offer contains the economic value without VAT. 2. The economic operator must draw up the economic offer independently.

b. *List of prices of articles, according to* ***Appendix 2***;

Argumentation: This appendix is part of the set of standard tender documents for the aforementioned procurement procedure.

c. *Summary Self-Declaration Form, according to* ***Appendix 9*****;**

Argumentation: This criterion was established with support in Article 76 of Law no. 162/2020 "On Public Procurement", and Article 26 of DCM no. 285, dated 19.05.2021 "For the Approval of Public Procurement Rules", in which it is determined that: "1. Together with the submission of requests for participation or offers, the contracting authority/entity accepts as preliminary evidence, instead of some certifications issued by public authorities or third parties, the self-declaration summary form, as defined in Article 82, of the PPL, and in these rules".

d. *Bid Security, according to* ***Appendix 3***;

2. The bidder must submit:

2.1. Compliance to perform the professional activity (if applicable):

a) The bidding economic operator must present the ***Certificate ISO 9001:2015 on "Quality management systems"*** *or* ***ISO 13485:2016 on "Quality Management System for Medical Devices",*** in accordance with the object of the procurement, issued by an assessment body of conformity, accredited by the national accreditation body or by the international accrediting body, recognized by the Republic of Albania. **The certificate is required to be valid at the time of the tender.**

Argumentation: The above request is based on article 77, points 1/a and 2, of PPL, article 41, point 4, of DCM no. 285, dated 19.05.2021 "On the approval of public procurement rules", as defined in point b) and c) was decided in accordance with point 1 of article 79 of Law no. 162/2020 "On Public Procurement", in which we find defined that:

1. The contracting authority or entity to prove that the works, goods or services, subject of procurement, meet the quality requirements, may ask the bidders to present certificates issued by a conformity assessment body, accredited by the national accreditation body or international accrediting bodies, recognized by the Republic of Albania.
This provision also applies when the technical requirements refer to the qualifications of the candidate or tenderer.
This criterion is also supported in the recommendation of APP and the General Directorate of Accreditation with protocol no. 3330, date 20.03.2018 and protocol no. 145, date 16.03.2018 "Recommendation on the drafting of quality requirements".

2.2. Economic and financial capacity:

a) Certification from the Tax Department for the annual turnover realized during the last 3 (three) financial years (**2020, 2021, and 2022**) where their value is not less than **40% of the value of the fund limit* of the lot or the amount of lots for which the operator competes.**

> ***Note****: For the purpose of calculating the required value according to this criterion, the average value will be applied on the value of the limit fund provided for according to the expected quantities of the lot/lots for which the offer is made, specifically on the values of the column "Expected value of contracts" in point 2.10 /or/ 2.14*
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> ***When competing for more than 1 lot, the average value will be applied over the total amount of the expected value of the contracts for the lots being competed for.***

If the economic operators, for the competing lot/lots, reach the value of the minimum turnover required in these TD, in at least one year of the required period, the requirement for completing the financial capacities is considered fulfilled.

Argumentation: This criterion is established in accordance with point 3 of article 77 of Law no. 162/2020, "On Public Procurement" as amended, in which we find that: 3. In relation to the economic and financial situation, the contracting authorities or entities may to establish requirements that guarantee that the economic operators have the necessary economic and financial capacity to implement the contract. For this purpose, authorities or contracting entities may require in particular that economic operators have a certain minimum annual turnover. Also, authorities or contracting entities may require economic operators to provide information in their annual balance sheets that show the ratios between assets and liabilities. The minimum annual turnover required by economic operators cannot exceed twice the estimated value of the contract.; in point 1 and point 2/b of article 43 of DCM no. 285 dated 19.05.2021 "For the Approval of the Public Procurement Rules", where it is determined that: Point 1. The contracting authority/entity, in order to prove the financial and economic capacities, requires copies of the annual turnover statements made by the economic operator and, according to in the case of

turnover covered by the contract, for a maximum period up to the last 3 (three) financial years. Point 2/b: 2. The value of the minimum annual turnover required of economic operators cannot exceed: b) the estimated value of the contract, in procurement procedures between the high and low monetary limits*;*

The establishment of this criterion is done with the aim of creating confidence in the Contracting Authority, for the economic and financial ability of the bidding EO, proving through the documents requested below, that they have the economic and financial capacity to fulfill the contract as provided by the CA.

The determination of the required value is argued as follows:

Legislator in point 1 and point 2/b of Article 43 of DCM no. 285 dated 19.05.2021 "For the Approval of Public Procurement Rules", provided for the maximum margin for the turnover value, which can be requested in the Open Procedure, where it is determined; Point 2/b: 2. The value of the minimum annual turnover required of economic operators cannot exceed: b) the estimated value of the contract, in procurement procedures between the high and low monetary limits; Since this procurement procedure is based on the value of the limit fund between the high and low monetary limit. CA is the only tertiary center in the Republic of Albania, for this reason the practice established over the years, which has been successful, is that of the maximum margins determined by the legislator in the Public Procurement Rules as well as in the Public Procurement Legislation as a whole.

Note: Since the legal and by-laws provide for a margin for the turnover value that can be claimed, contracting authorities/entities must justify the required turnover value within this margin.

The determination of the years required for the presentation of the certification of the annual turnover is based on Article 43 of DCM 285/2021 'On the Rules of Public Procurement', which states that: The contracting authority/entity, in order to prove the financial and economic capacities, requires copies of declarations of the annual turnover realized by the economic operator and, in the case of the turnover covered by the contract, for a maximum period up to the last 3 (three) financial years; as well as Article 13 of Law no. 8438, dated 28.12.1998 "On Income Tax" as amended, which defines the conditions and deadlines for submission of individual annual income statements; (Note: cite the relevant provision of the tax legislation, which defines the deadlines for submission by taxpayers of the annual declaration to the tax authorities*).*

2.3 Technical and professional skills:

a) Evidence from the economic operator for previous similar **services** in the amount of **20% of the value of the limit fund* of the lot or the sum of the lots for which the operator competes** and **which was realized during the last three years, from the date of the announcement of the notice of contract.**

- As proof of previous experience with a public entity, **certificates* issued by a public entity for the successful fulfillment of the contract are required, together with the relevant contract, where the value, the deadline for the completion of the contract and/or the tax invoice of the of sale where the dates, amounts and services performed are noted.**

In the case of previous experience with the private sector, **only sales tax invoices, completed according to the requirements of the legislation in force, and declared to the tax authorities, where the dates, amounts and services performed**, are accepted as evidence.

Note*: For the purpose of calculating the required value according to this criterion, 20% will be applied on the value of the limit fund provided according to the expected quantities of the lot/lots for which the offer is made, **specifically on the values of the column "Expected value of contracts" in point 2.10 / 2.14**.

When competing for more than 1 lot, 20% will be applied on the total amount of the expected value of the contracts for the lots being competed for.

Argumentation: This criterion was established in accordance with point 4 of article 77 of Law no. 162/2020, "On Public Procurement", in which we find that: 4. In relation to technical and professional skills, authorities or contracting entities can establish requirements that guarantee that economic operators possess the necessary human and technical resources, such as and the experience necessary to implement the contract according to an appropriate quality standard. Contracting authorities or entities, in particular, may require that economic operators have a sufficient level of experience that is proven by appropriate references from contracts implemented in the past. The professional ability of economic operators to provide the service, work, goods is assessed in relation to organizational skills, reputation and reliability, appropriate experience, as well as the necessary personnel to implement the contract, as described by the contracting authority or entity in the notification of the object of the contract; as well as Article 41 of DCM no. 285 dated 19.05.2021 "For the Approval of Public Procurement Rules", in which it is determined that: [...]3. To prove previous experience, the contracting authority/entity requires evidence of the successful completion of one or more contracts for previous, similar services performed during the last three years*. In any case, the requested value must be in a value not greater than 40% of the estimated value of the contract that is being procured and that has been realized during the last three years, from the date of the announcement of the contract notice. The contracting authority/entity, as proof of previous experience, requires certificates issued by a public entity for the successful fulfillment of the contract, where the value, the deadline for the completion of the contract, or/and sales tax invoices, completed according to the requirements of legislation in force, where the dates, amounts and services performed are noted. In the case of previous experience with the private sector, only sales tax invoices, completed according to the requirements of the legislation in force, and declared to the tax authorities, where the dates, amounts and services performed, are accepted as evidence. In the case of procurement procedures "Consulting service", as previous experience for services similar to the object of procurement will be recognized and/or services similar to the relevant areas of expertise, part of the object of procurement.*

The establishment of this criterion is done with the aim of creating confidence in the Contracting Authority, for the technical ability of the bidding EO, through the appropriate experiences, which are proportional to the nature of the procurement object and that it has the appropriate ability to implement the contract as provided by CA.

The determination of the required value for similar contracts is argued as follows: The above request is determined based on Article 77 of Law No. 162, dated 23.12.2020 "On Public Procurement", Article 41 of DCM No. 285, dated 19.05.2021 "For Approval of Public Procurement Rules". By means of this criterion, it is required that the economic operators prove that they have the necessary experience to implement the contract, therefore it is requested that the previous similar supplies be in the value of no less than 20% of the value of the limit fund, which is within limit value defined in the above-mentioned article. The Contracting Authority QSU "Mother Teresa" Tirana is a tertiary National Public Health institution in the service of the health of the population, which provides preventive, diagnostic and curative health services according to the Constitution of Albania and public health laws. The establishment of this criterion is done with the aim of creating of obedience to the Contracting Authority, for the technical ability of the bidding EO, through appropriate experiences, which are proportional to the nature of the procurement object and which has the appropriate ability to implement the contract as provided by the CA.

b) The Economic Operator must prove that it has at least **1 (one)* Engineers/Specialists** in its staff trained for medical equipment who will perform the maintenance service and supply and placement of spare parts, proven through: diploma, certificate of training, CV, individual work contract. Only this staff will perform preventive, corrective and calibration maintenance interventions on medical equipment.

***Note:** With this minimum required number, it is intended to guarantee the provision of the service at all times and prevent the cases of the impossibility of staff presence for various objective reasons (annual leave, medical report, training, etc.).*

***Note:** This criterion in the bidding phase of the economic operators will be considered fulfilled with the submission/presentation of the summary self-declaration form according to Appendix 9 of the STD. In cases where the EO will be declared the winner, it must submit the proof documentation according to this criterion.*

Argumentation: This criterion was established in support of Letter no. 1232/15 prot.., dated 07/06/2023 "Request for Opening Procedure" from the Directorate of IT and Clinical Engineering, with the object "Full-Risk Maintenance of medical devices manufactured by GE (or equivalent), for the needs of QSUNT for 24 months, connection to the argumentation of needs for (24 months), technical specifications and limit fund with no. 1232/14 prot., date 04/07/2023, according to Internal Order with Order No. 471, with no. 1232/4 prot., dated 21/06/2023, amended Order No. 488, with no. 1232/10 prot., dated 03/07/2023, "On the establishment of the working group for the calculation of the limit fund, the drafting of technical specifications and the argumentation of the needs for the procurement procedures with objects 'Maintenance of large medical materials of the manufacturer Philips / or equivalent, manufacturers Siemens / or equivalent and manufacturers Toshiba / or equivalent' for 24 months", as well as the letter of the Ministry of Education and Culture with no. 541/14 prot., dated 12.06.2023, administered at QSU "Mother Teresa" with no. 1232 prot., dated 13/06/2023

"The right to perform procurement procedures is delegated", where as regards the equipment of other manufacturers, the CA must continue with the procurement procedure was argued/drafted from the members of the Procurement Unit who have the relevant specialties in relation to the technical criteria, as criteria established in accordance with point 4 of article 77 of Law no. 162, dated 23.12.2020 "On Public Procurement", in Article 41, of DCM 285, dated 19.05.2021 "On the Approval of Public Procurement Rules", where all possible criteria that the contracting authority deems necessary are defined, for as long as they are proportionate to the nature and size of the contract to be procured and non-discriminatory. For this procedure, the object of the procurement is: Maintenance of large medical equipment of the manufacturer Philips/or equivalent, manufacturer Siemens/or equivalent, and manufacturer Toshiba/or equivalent" for 24 months", divided into lots (total 2). This criterion, specifically, has been established so that the entire procedure is carried out by persons qualified who guarantee the implementation of the contract completely and in the right way, throughout its duration. This criterion has been approved and established by the members of the Procurement Unit who have the relevant specialty in relation to Qualification Requirements, in accordance with Article 77 point 4, of Law No. 162/2020 "On Public Procurement". This criterion is also supported in APP Recommendation No. 8197, dated 03.09.2018 Prot "On the drafting of qualification criteria for procurement procedures for goods, works, services". This criterion is supported in DCM no. 285 dated 19.05.2021 "On the Approval of Public Procurement Rules" of Article 41 "Special requirements for service contracts", point 4, where it is determined that: To prove the suitability to perform the professional activity, the technical and professional capacities, the contracting authority/entity requires: a) professional license for the realization of the services, subject of the contract , issued by the competent state authorities; and/or, b) a list of key personnel needed to implement the procurement object and/or its components. The list of key personnel must include their CVs and professional licenses, when they have such according to the relevant legislation; and/or, c) the workforce of the economic operator necessary for the execution of the procurement object; and/or, ç) the means and technical equipment available or that can be made available to the economic operator to fulfill the contract.

c) The bidding economic operator must present an ***Authorization from the manufacturer / MAH / or from the official distributor authorized by the manufacturer (where their relationship with the manufacturer is proven/documented),*** to guarantee quality, safe maintenance and original parts of the medical equipment object in this procurement procedure. The authorization must be original and if it is not in English or Albanian, it must be translated into English or Albanian and notarized, as well as be valid at the time of opening the bids.

Argumentation*: This criterion was established in support of Letter no. 1232/15 prot.., dated 07/06/2023 "Request for Opening Procedure" from the Directorate of IT and Clinical Engineering, with the object "Full-Risk Maintenance of medical devices manufactured by GE (or equivalent), for the needs of QSUNT for 24 months, connection to the argumentation of needs for (24 months), technical specifications and limit fund with no. 1232/14 prot., date 04/07/2023,*

according to Internal Order with Order No. 471, with no. 1232/4 prot., dated 21/06/2023, amended Order No. 488, with no. 1232/10 prot., dated 03/07/2023, "On the establishment of the working group for the calculation of the limit fund, the drafting of technical specifications and the argumentation of the needs for the procurement procedures with objects 'Maintenance of large medical materials of the manufacturer Philips / or equivalent, manufacturers Siemens / or equivalent and manufacturers Toshiba / or equivalent' for 24 months", as well as the letter of the Ministry of Education and Culture with no. 541/14 prot., dated 12.06.2023, administered at QSU "Mother Teresa" with no. 1232 prot., dated 13/06/2023 "The right to perform procurement procedures is delegated", where in terms of equipment from other manufacturers, the CA must continue with the procurement procedure, it was approved by the members of the Procurement Unit who have the relevant specialty in relation to the technical criteria. Also, this criterion finds support in points 2 and 4 of article 77 of law no. 162, dated 23.12.2020 "On public procurement" and point 5 of Article 44 of DCM no. 285 dated 19.05.2021 "On the Approval of Public Procurement Rules", where it is quoted: 5. When it is obvious that an economic operator it is impossible to obtain the specific label, designated by the contracting authority/entity or an equivalent label, within the relevant time limits, for reasons not related to that economic operator, the contracting authority or entity accepts other appropriate means of authentication, which may include a technical file from the manufacturer, if the economic operator in question certifies that the works, supplies or services he has to provide meet the requirements of the specific label or the specific requirements specified by the contracting authority/entity.

*The authorization for the bidding EO from the manufacturing company or from the distributor authorized by the manufacturer is a necessary document to be presented, so that the contracting authority can ensure that the entity/company that has this document guarantees quality, safe maintenance and original parts of medical equipment subject to this procurement procedure. As well as this criterion was decided in support of Recommendation no. 3341/1 prot. Date 20.03.2018 of the Public Procurement Agency (Legal and Monitoring Directorate) to the Contracting Authorities "Recommendation on the drafting of criteria for qualification in tender documents of public procurement procedures".***

d) EO must submit a ***Self-declaration that undertakes the supply/replacement of spare parts and accessories and that:***

- Materials and spare parts must be new, original or from other certified manufacturers, and always consistent with those originally used in the equipment, ensuring conformity with the instructions given by the manufacturer in the technical documentation supplied with the equipment.
- To be CE or FDA certified according to standards and directives approved in the European market.
- Where applicable, spare parts and accessories must have an accompanying installation manual according to the manufacturer's recommendations. A copy of this document is submitted to the representative of the Contracting Authority.

- The parts must have no less than 1 (one)* year warranty including all their possible defects.

(Clarification: The warranty period of the spare parts may exceed the term of this contract. The contractor is obliged to maintain, according to the terms of the warranty, the spare part even after the term of the end of this contract if the defect of the part occurs within the one-year term of spare part warranty.)

e) The EO must submit a Self-declaration where it declares that it will conduct a safety inspection of medical equipment, **at least 1 (one) a safety inspection according to the international electrical standard IEC 62353, or the equivalent SSH standard**, specified by the MDD Medical Devices Directive (or MDR) 98/79 EC (updated/ as far as applicable/valid), or EU 2016/425 (updated/ as far as applicable/valid), or FDA or (EU) 2017/ 745, when applicable, according to the Directives and classification of the Council of Europe, for any medical device and its components during the period of this contract, through trained and certified staff, when applicable. The inspection includes:

- The Economic Operator must perform visual inspection, tests, and measurements with calibrated devices.
- The Economic Operator must plan the performance of these tests in collaboration with the staff of the Clinical Engineering Sector based on the manufacturer's specifications.
- At the end of each safety inspection, a descriptive report must be compiled and signed by the specialists of the Clinical Engineering Sector and the Engineer/Technician of the company (OE) that performs the test.
- After each security test, a sign indicating the security status of the device must be placed on the device.
- In addition to the aforementioned cases, the safety verification inspection service must also be performed after corrective maintenance, when applicable.
- The Contracting Authority has the right to request verifications in addition to the planned ones, in special cases, under conditions or according to special needs, and the Contractor is obliged to accept these requests unconditionally".

Argumentation: *This criterion was drawn up by the member of the Procurement Unit who has the relevant specialty in relation to technical criteria and was decided referring to request no. 1232/15 prot.., dated 07/06/2023 "Request for Opening Procedure" from the Directorate of IT and Clinical Engineering, with the object "Full-Risk Maintenance of medical devices manufactured by GE (or equivalent), for the needs of QSUNT for 24 months, connection to the argumentation of needs for (24 months), technical specifications and limit fund with no. 1232/14 prot., date 04/07/2023, according to Internal Order with Order No. 471, with no. 1232/4 prot., dated 21/06/2023, amended Order No. 488, with no. 1232/10 prot., dated 03/07/2023, "On the establishment of the working group for the calculation of the limit fund, the drafting of technical specifications and the argumentation of the needs for the procurement procedures with objects 'Maintenance of large medical materials of the manufacturer Philips / or equivalent, manufacturers Siemens / or equivalent and manufacturers Toshiba / or equivalent' for 24 months", as well as the letter of the Ministry of Education and Culture with no. 541/14 prot., dated 12.06.2023, administered at QSU "Mother Teresa" with no. 1232 prot., dated 13/06/2023 "The right to perform procurement procedures is delegated",, where as for equipment from other*

manufacturers, CA must continue with the procurement procedure. Also, the establishment of this criterion is in accordance with Article 38, Article 36 and 77 of Law no. 162/2020, "On Public Procurement", in Article 41 of DCM no. 285, dated 19.05.2021 "On the Approval of Public Procurement Rules", amended, APP recommendation no. 3341/1 prot, dated 20.03.2018 "On the drafting of criteria for qualification in tender documents of public procurement procedures", recommendation of APP and the General Directorate of Accreditation no. 3330 prot, dated 20.03.2018 and no. 145 prot, dated 16.03.2018 "Recommendation on the drafting of quality requirements", Self-declaration by the bidder who undertakes the replacement of spare and consumable parts, that they will be new and original and in accordance with those originally used (guaranteed through CE or FDA certification) is a necessary document to present, so that the contracting authority can ensure that the entity/company that will perform the maintenance/repair service provides the guarantee of the repair of these devices, in necessary cases, according to the requirements defined in the tender documents. We emphasize that medical devices are very specific and their repair requires specific original parts of the device itself, for a full operation, certified with CE to guarantee their full quality.

f) The EO must submit a Self-Declaration guaranteeing that in the event of being declared the winner, it will perform the ***maintenance service***, repair and replacement of any defect/possible part/during the contract period, for the equipment and all accessories ***which are connected with the device***, so that it is at the service of the staff and which directly affect the operation of the device within the standards set by the manufacturer.

g) The Bidder (Economic Operator) must issue a Declaration by means of which it **undertakes the technical insurance of its staff** during the working time in the premises of QSUNT, and the latter bears no responsibility for the accidents that happened to the employees of the Economic Operator in its premises.

h) EO must submit Self-Declaration by means of which **to define more than one contact person for reporting defects** and administrative issues, for which you must inform the Contracting Authority (phone and email). Any change of contact must be immediately reported in writing to the parties. The staff (of the Contractor) must be equipped with a personal identification card (tool) during visits to the Contractor's premises and be accompanied by the staff of the Clinical Engineering Department.

Argumentation: The criteria established in the STD in points f), g), and h) were established by the members of the PU who have the relevant specialty in relation to the technical criteria and is in accordance with article 38, article 36 and 77 of Law no. 162/2020, "On Public Procurement", in article 41 of DCM no. 285, dated 19.05.2021 "On the Approval of Public Procurement Rules", APP recommendation no. 3341/1 prot, dated 20.03.2018 "On the drafting of criteria for qualification in the tender documents of public procurement procedures", the recommendation of PPA and the General Directorate of Accreditation no. 3330 prot, dated 20.03.2018 and no. 145 prot, dated 16.03.2018 "Recommendation on the drafting of quality requirements", as well as referring to letter *no. 1232/15*

prot.., dated 07/06/2023 "Request for Opening Procedure" from the Directorate of IT and Clinical Engineering, with the object "Full-Risk Maintenance of medical devices manufactured by GE (or equivalent), for the needs of QSUNT for 24 months, connection to the argumentation of needs for (24 months), technical specifications and limit fund with no. 1232/14 prot., date 04/07/2023, according to Internal Order with Order No. 471, with no. 1232/4 prot., dated 21/06/2023, amended Order No. 488, with no. 1232/10 prot., dated 03/07/2023, "On the establishment of the working group for the calculation of the limit fund, the drafting of technical specifications and the argumentation of the needs for the procurement procedures with objects 'Maintenance of large medical materials of the manufacturer Philips / or equivalent, manufacturers Siemens / or equivalent and manufacturers Toshiba / or equivalent' for 24 months", as well as the letter of the Ministry of Education and Culture with no. 541/14 prot., dated 12.06.2023, administered at QSU "Mother Teresa" with no. 1232 prot., dated 13/06/2023 "The right to perform procurement procedures is delegated", where as for equipment from other manufacturers, CA must continue with the procurement procedure. Warranty statement for, maintenance service, repair and replacement of any possible defects/parts/during the contract period, for the equipment and all accessories which are connected to the equipment, so that it is at the service of the staff and which directly affect the operation of the device within the standards set by the manufacturer, is defined according to the definition of the technical specifications, the requirements in order to guarantee the fulfillment of the requirements of the CA specified in relation no. 1232/14 prot., date 04/07/2023.

Note for economic operators:

Pursuant to point 1, Article 26, of DCM No. 285, dated May 19, 2021 "On the adoption of public procurement rules" as amended, which stipulates: "Together with the submission of requests for participation or offers, the contracting authority/entity accepts as preliminary evidence, instead of certain certificates issued by public authorities or third parties, the self-declaration summary form, as defined in article 82 of the PPL, and in these rules", as well as the definitions of point 6 of this article, which stipulates: *"Before the publication of the winner's announcement and the start of the appeal deadlines, the contracting authority/entity asks the qualified bidder, first, to submit the proof documents provided for in the letters "a", "b", "d", "dh", "e", "h" , "i", "j" of point 2 of this article, as well as other documents accompanying the offer, submitted electronically. These documents must be presented in original or in copies identical to the original.*

- The contracting authority/entity, before the publication of the notice of the winner and the start of the appeal deadlines, will ask the winning bidder through the Electronic Procurement System to submit the proof documents for the self-declarations made in the summary self-declaration form, as well as other documents of required under Schedule 9 of the STD. Failure to submit documentation to meet these points will be a condition of disqualification.

- The Contracting Authority can verify the documentation in accordance with the self-declaration made during the bidding phase. Finding inconsistencies between the Summary Self-Declaration Form and the submitted documentation is a condition for disqualification.
- In any case, the CA has the right to perform the necessary verifications on the authenticity of the information declared by the economic operator or to ask the economic operator for clarifications and supporting documents for these clarifications.

II. Argumentation of technical specifications

TECHNICAL SPECIFICATIONS AND TERMS OF REFERENCE:

(SAME FOR ALL LOTS)

General Technical Specifications

1. The Economic Operator must submit the Authorization from the manufacturer / MAH / or distributor i
2. The Economic Operator must have more than one contact person for reporting defects and administrative issues, for which the Contracting Authority must be notified (phone and email).
3. Any change of contact must be reported immediately in writing to the parties.
4. The staff (of the Contractor) must be equipped with a personal identification card (tool) during visits to the Contractor's premises and be accompanied by the staff of the Clinical Engineering Sector.
5. The Bidder (Economic Operator) must issue a Declaration by means of which he undertakes the technical insurance of his staff during the working time in the premises of QSUNT, and the latter bears no responsibility for the accidents that happened to the Operator's employees Economic in its premises.

Preventive maintenance of medical equipment

1. Preventive or preventive maintenance of medical equipment must be carried out in accordance with the recommendations of the relevant manufacturer to prevent defects related to their use and component parts, to maintain the equipment in proper operating condition, to ensure quality and reliability of results, to highlight conditions such as aging or performance deterioration.
2. The Economic Operator (Bidder) must submit the Recommendations from the manufacturer of the device/s and a preventive maintenance action plan that defines the periodicity, operating procedures and protocols it intends to use, including calibrations.
3. With the conclusion of the contract, preventive maintenance must be performed for each device, according to the presented plan. The Economic Operator (EO) must plan and coordinate preventive maintenance in cooperation with the staff of the Clinical Engineering Department and the user (medical staff), and perform it no later than 30 days from the start of the contract.
4. Regardless of the planned preventive maintenance plan, the EO must perform a monthly periodic control of the operation of the device.
5. At the end of any check or preventive maintenance carried out, a report must be kept on the fact. The report must be signed by the representative of the Service where the device is located, the representative

of the Clinical Engineering Sector and the EO Engineer/Technician who will perform the inspection/maintenance. The model of this report is standardized by CA.
6. The Contracting Authority has the right to request controls or verifications other than those planned, in special cases, under conditions or according to special needs, and the Contractor is obliged to accept these requests unconditionally.

Corrective Maintenance of Medical Equipment

1. Corrective maintenance interventions consist of determining the presence of a defect or malfunction, identifying the causes, eliminating them and restoring the original characteristics, to guarantee the integrity of the equipment, its operation and safety.

2. The contracted company (CO) must carry out the maintenance service, repair and replacement of any possible defect/part during the contract period, for the equipment and all accessories which are connected to it, so that it to be at the service of the medical staff, such as: X-ray tubes, Detectors, Computers, Hard Drive, DVD-CD, Keyboard, Monitor, RAM, Ups, Power supply, printer, network infrastructure, chips, probes, cuffs, sensors, electrodes, gears, electronic, electrical, mechanical, hydraulic parts, valves, mechanical parts, wheels, pistons, motors, etc., and directly affect the operation of the device within the standards set by the manufacturer.

3. The contracted company (OE) must appear to check and verify the defect within 2 hours of receiving notifications (by e-mail and/or phone to the contact details provided) from the Clinical Engineering Sector about the normal malfunction, various problems or device defects.

4. In the case where spare parts are not needed, the correction of the defect must be carried out no later than 48 hours after receiving the notification.

5. In case it is determined that spare parts are needed to correct a defect, the EO must supply and install the spare parts, repair the defect and put the equipment in normal working condition within 7 calendar days from the date of drawing up the minutes, standardized by CA, for the need of spare parts signed by the specialist of the Clinical Engineering Sector, the medical staff using the device and the engineer of the contracted Company (OE).

6. The contracted company (OE) must guarantee that it will not exceed the deadline of 10 days for putting the device/s into operation.

7. After the repairs or interventions performed, the contracted company (OE) must perform the necessary calibrations, the verification of the parameters as recommended by the manufacturer, to guarantee the normal operation of the device.

8. After any repair, replacement of spare parts or accessories, the device must be restored to full working order.

9. The movement, displacement, disassembly and reassembly of equipment parts during corrective maintenance is under the charge and responsibility of the Contractor.

10. After every repair or replacement of parts, a record (standardized by the CA) or Service Report, the format of which is approved and unified by the CA, must be kept, which describes in detail and clearly the defect/problem, the replaced parts if any, calibrations and function test. The Service Report must be signed by the Head of the Service where the device is located or persons authorized by him (medical staff using the device), the specialist of the Clinical Engineering Department and the technician or engineer of the company contracted for maintenance.

11. The contracted company will enable movement, relocation, disassembly and reassembly only once for each device of the equipment group if this is required by the Contracting Authority.

Supply of spare parts and accessories

1. Materials and spare parts must be new, original or from other certified manufacturers, and always consistent with those originally used in the device, ensuring conformity with the instructions given by the manufacturer in the technical documentation supplied with the device.

2. To be CE or FDA certified according to the standards and directives approved in the European market.

3. Where applicable, spare parts and accessories shall have accompanying installation manuals as per manufacturer's recommendations. A copy of this document is submitted to the representative of the Contracting Authority.

4. The parts must have no less than 1 (one)* year warranty including all their possible defects.

   (Clarification: The warranty period of the spare parts may exceed the term of this contract. The contractor is obliged to maintain, according to the terms of the warranty, the spare part even after the term of the end of this contract if the defect of the part occurs within the one-year term of spare part warranty/ or reaching the maximum wear certified by the manufacturer.)

Safety inspection of medical devices

The Economic Operator must perform at least 1(one) a safety inspection according to the international electrical standard IEC 62353 specified by the Medical Devices Directive MDD (or MDR) 98/79 EC (updated), or EU 2016/425 (updated) or FDA or (EU) 2017/745, when applicable, according to the Directives and classification of the Council of Europe, for any

medical device and its components during the period of this contract, through trained and certified staff, when this is applicable.

1. The Economic Operator must perform visual inspection, tests and measurements with calibrated devices.

2. The Economic Operator must plan the performance of these tests in collaboration with the staff of the Clinical Engineering Department based on the manufacturer's specifications.

3. At the end of each safety inspection, a descriptive report must be drawn up and signed by the specialists of the Clinical Engineering Department and the Engineer/Technician of the company (OE) performing the test.

4. After each security test, a sign indicating the security status of the device must be placed on the device.

5. In addition to the aforementioned cases, the safety verification inspection service must also be performed after corrective maintenance, when applicable.

6. The Contracting Authority has the right to request verifications other than those planned, in special cases, under conditions or according to special needs, and the Contractor is obliged to accept these requests unconditionally.

Argumentation: This criterion was established in support of Letter *no. 1232/15 prot.., dated 07/06/2023 "Request for Opening Procedure" from the Directorate of IT and Clinical Engineering, with the object "Full-Risk Maintenance of medical devices manufactured by GE (or equivalent), for the needs of QSUNT for 24 months, connection to the argumentation of needs for (24 months), technical specifications and limit fund with no. 1232/14 prot., date 04/07/2023, according to Internal Order with Order No. 471, with no. 1232/4 prot., dated 21/06/2023, amended Order No. 488, with no. 1232/10 prot., dated 03/07/2023, "On the establishment of the working group for the calculation of the limit fund, the drafting of technical specifications and the argumentation of the needs for the procurement procedures with objects 'Maintenance of large medical materials of the manufacturer Philips / or equivalent, manufacturers Siemens / or equivalent and manufacturers Toshiba / or equivalent' for 24 months", as well as the letter of the Ministry of Education and Culture with no. 541/14 prot., dated 12.06.2023, administered at QSU "Mother Teresa" with no. 1232 prot., dated 13/06/2023 "The right to perform procurement procedures is delegated"*, where in terms of equipment from other manufacturers, CA must continue with the procurement procedure, as well as in compliance with article 4, item 38 of Law no. 162/2020, "On Public Procurement", Article 41, of DCM no. 285, dated 19.05.2021, "On the approval of public procurement rules".

Appendix 6

SERVICES FORM AND EXECUTION SCHEDULE

(SAME FOR ALL LOTS)

Service required: facility **Maintenance of large medical equipment of the manufacturer Philips/or equivalent, manufacturer Siemens/or equivalent, and manufacturer Toshiba/or equivalent" for 24 months", divided into lots (total 2).**

Loi 1 - Medical device manufacturer Philips /or equivalent									
Inventory no.	**Device Name**	**Manufacturer**	**Model**	**Serial no.**	**Location**	**Service**	**Quantity**	**Price for one day of service**	**Total Days for 24 months or (730 days)**
31501	Angiography	Philips	Allura Centron	1233	Central Hospital	Hemodynamics Service	1		
20178	Angiography	Philips	Allura CV 20	155	Central Hospital	Hemodynamics Service	1		
19887	Scanner	Philips	Big Bore	750009	PAI Oncology	Oncology Service	1		
19854	Magnetic Resonance	Philips	Pulsera 1,5T	30201	PAI Polyvalent	Imaging Service	1		
32744	Magnetic Resonance	Philips	Ingenia 3,0T		PAI of Neuroscience	Neurology Service	1		
Value without VAT									
VAT									
Value with VAT									
Lot 2 - Medical device manufacturer Siemens /or equivalent									
Inventory no.	**Device Name**	**Manufacturer**	**Model**	**Serial no.**	**Location**	**Service**	**Quantity**	**Price for one day of service**	**Total Days for 24 months or (730 days)**
21410	Accelerator Linear	Siemens	Oncor Impression Pluss	5884	PAI of Neuroscience	Neurosurgery Service	1		
19268	Angiography	Siemens	Artis DFA	50109	PAI of Neuroscience	Neurology Service	1		
19228	Scanner	Siemens	Somatom Emotion	8004	PAI of Neuroscience	Neurology Service	1		

21437	Scanner	Siemens	Definition AS	66090	Central Hospital	Imaging Service	1		
19208	Scanner	Siemens	Volum Sim Emotion	46737	PAI Oncology	Oncology Service	1		
Value without VAT									
VAT									
Value with VAT									

Note: The offer submitted by the interested economic operators must present the price/value per day of service.

Execution deadlines:

Duration of the contract: 24 months from the conclusion of the Framework Agreement (or 730 days from the conclusion of the FA).

The contracts will be awarded within the period, from the moment of the connection of FA with the winning EO for each lot, with a final deadline of 24 months or 730 from the connection of FA

Appendix 7

TERMS OF REFERENCE FORM

(SAME FOR ALL LOTS)

Scope and purpose of services: Maintenance of large medical equipment of the manufacturer Philips/or equivalent, manufacturer Siemens/or equivalent, and manufacturer Toshiba/or equivalent" for 24 months", divided into lots (total 2).

Preventive maintenance of medical equipment

1. Preventive maintenance of medical equipment must be carried out in accordance with the recommendations of the relevant manufacturer to prevent defects related to their use and component parts, to maintain the equipment in proper operating condition, to ensure quality and reliability of results, to highlight conditions such as aging or performance deterioration.

2. The Economic Operator must certify that it has at least 1 (one) Engineer/Specialist in its staff trained for the medical equipment subject to procurement, proven through: diploma, training certificate, CV, individual employment contract. Only this staff will perform preventive, corrective and calibration maintenance interventions on medical equipment.

3. The Economic Operator (Bidder) must submit the Recommendations from the manufacturer of the device/s and a preventive maintenance action plan that defines the periodicity, operating procedures and protocols it intends to use, including calibrations.

4. With the conclusion of the contract, preventive maintenance must be performed for each device, according to the presented plan. The Economic Operator (EO) must plan and coordinate preventive maintenance in cooperation with the staff of the Clinical Engineering Department and the user (medical staff), and carry it out no later than 30 days from the start of the contract.

5. Regardless of the planned preventive maintenance plan, the EO must perform a monthly periodic control of the operation of the device.

6. At the end of any check or preventive maintenance performed, a report must be kept on the fact. The report must be signed by the representative of the Service where the device is located, the representative of the Clinical Engineering Sector and the EO Engineer/Technician who will perform the inspection/maintenance. The model of this report is standardized by CA.

7. The Contracting Authority has the right to request controls or verifications other than those planned, in special cases, under conditions or according to special needs, and the Contractor is obliged to accept these requests unconditionally.

Corrective Maintenance of Medical Equipment

12. Corrective maintenance interventions consist of determining the presence of a defect or malfunction, identifying the causes, eliminating them and restoring the original characteristics, to guarantee the integrity of the equipment, its operation and safety.

13. The contracted company (OE) must carry out the maintenance service, repair and replacement of any defect/possible/part during the contract period, for the equipment and all accessories which are connected to it, so that it to be at the service of the medical staff, such as: X-ray tubes, Detectors, Computers, Hard Drive, DVD-CD, Keyboard, Monitor, RAM, Ups, Power supply, printer, network infrastructure, chips, probes, cuffs, sensors, electrodes, gears, electronic, electrical, mechanical, hydraulic parts, valves, mechanical parts, wheels, pistons, motors, etc., and directly affect the operation of the device within the standards set by the manufacturer.

14. The contracted company (OE) must appear to check and verify the defect within 2 hours of receiving notifications (by e-mail and/or phone to the contact details provided) from the

Clinical Engineering Sector about the normal malfunction, various problems or device defects.

15. In the event that spare parts are not required, the correction of the defect must be carried out no later than 48 hours after receiving the notification.

16. In case it is determined that spare parts are needed to correct a defect, the EO must supply and install the spare parts, repair the defect and put the equipment in normal working condition within 7 calendar days from the date of drawing up the minutes, standardized by CA, for the need of spare parts signed by the specialist of the Clinical Engineering Sector, the medical staff using the device and the engineer of the contracted Company (OE).

17. The contracted company (OE) must guarantee that it will not exceed the deadline of 10 days for putting the device/s into operation.

18. After the repairs or interventions performed, the contracted company (OE) must perform the necessary calibrations, the verification of the parameters as recommended by the manufacturer, to guarantee the normal operation of the device.

19. After any repair, replacement of spare parts or accessories, the device must be restored to full working order.

20. Movement, displacement, disassembly and reassembly of equipment parts during corrective maintenance is the responsibility and responsibility of the Contractor.

21. After every repair or replacement of parts, a record (standardized by CA) or Service Report, the format of which is approved and unified by CA, describing in detail and clearly the defect/problem, the replaced parts must be kept if any, calibrations and function test. The Service Report must be signed by the Head of the Service where the device is located or persons authorized by him (medical staff using the device), the specialist of the Clinical Engineering Department and the technician or engineer of the company contracted for maintenance.

22. The contracted company will enable only once for each device of the equipment group the movement, relocation, disassembly and reassembly if this is required by the Contracting Authority.

Supply of spare parts and accessories

5. Materials and spare parts must be new, original or from other certified manufacturers, and always consistent with those originally used in the device, ensuring conformity with the instructions given by the manufacturer in the technical documentation supplied with the device.

6. To be CE or FDA certified according to the standards and directives approved in the European market.

7. Where applicable, spare parts and accessories shall have accompanying installation manuals as per manufacturer's recommendations. A copy of this document is submitted to the representative of the Contracting Authority.

8. The parts must have no less than 1 (one)* year warranty including all their possible defects.

(Clarification: The warranty period of the spare parts may exceed the term of this contract. The contractor is obliged to maintain, according to the terms of the warranty, the spare part even after the term of the end of this contract if the defect of the part occurs within the one-year term of spare part warranty/ or reaching the maximum wear certified by the manufacturer.

Safety inspection of medical devices

The Economic Operator must perform at least 1(one) a safety inspection according to the international electrical standard IEC 62353 specified by the Medical Devices Directive MDD (or MDR) 98/79 EC (updated), or EU 2016/425 (updated) or FDA or (EU) 2017/745, when applicable, according to the Directives and classification of the Council of Europe, for any medical device and its components during the period of this contract, through trained and certified staff, when this is applicable.

7. The Economic Operator must perform visual inspection, tests and measurements with calibrated devices.

8. The Economic Operator must plan the performance of these tests in collaboration with the staff of the Clinical Engineering Department based on the manufacturer's specifications.

9. At the end of each safety inspection, a descriptive report must be drawn up and signed by the specialists of the Clinical Engineering Department and the Engineer/Technician of the company (OE) performing the test.

10. After each safety test, a sign indicating the safety status of the device must be placed on the device.

11. In addition to the aforementioned cases, the safety verification inspection service must also be performed after corrective maintenance, when applicable.

12. The Contracting Authority has the right to request verifications other than those planned, in special cases, under conditions or according to special needs, and the Contractor is obliged to accept these requests unconditionally.

Execution deadlines: The maintenance service will be performed from the conclusion of the contract within FA with a term of 24 months from the framework agreement. The service will be provided according to the Mini-Contracts concluded within FA.

Assignments: Complete maintenance of equipment means to carry out preventive maintenance as specified by the manufacturer, corrective maintenance of each equipment and component parts for any possible defect without excluding specific parts, electrical safety inspection of medical equipment, supply and replacement of spare parts and accessories as well as transfer and installation upon request by the Contracting Authority.
Distribution: In the buildings of the "Mother Teresa" Tirana Hospital, in all the services where the medical equipment is located, which are defined in the detailed tables and will be refreshed at the time of signing the contract with the winning Economic Operator.
Place of performance of services: "Mother Teresa" University Hospital Center, Tirana.
Note: CA enjoys the right to exclude from maintenance, one or several devices subject to service in this procurement procedure, in case the device is end-of-support, and EO will accept it without consequences for CA.

The contracts will be awarded within the period, from the moment of the connection of the MK with the winning EO for each lot, with a final deadline of 24 months or 730 from the connection of the MK.
Contracts will be concluded according to lots, with separate items, based on the warranty period and the "Full Risk" coverage period from the manufacturer.
Contracts will be concluded, at the request of the Directorate of IT and Clinical Engineering, based on the period of coverage of the service, determined by this directorate, for each calendar day, within the period of the Framework Agreement.

Argumentation: The contracts will be awarded within the period: Execution deadlines:
Maintenance of large medical equipment of the manufacturer Philips/or equivalent, manufacturer Siemens/or equivalent, and manufacturer Toshiba/or equivalent" for 24 months", divided into lots (total 2).
Quantity and Chart of Delivery: have been decided on the basis of Letter *no. 1232/15 prot.., dated 07/06/2023 "Request for Opening Procedure" from the Directorate of IT and Clinical Engineering, with the object "Full-Risk Maintenance of medical devices manufactured by GE (or equivalent), for the needs of QSUNT for 24 months, connection to the argumentation of needs for (24 months), technical specifications and limit fund with no. 1232/14 prot., date 04/07/2023, according to Internal Order with Order No. 471, with no. 1232/4 prot., dated 21/06/2023, amended Order No. 488, with no. 1232/10 prot., dated 03/07/2023, "On the establishment of the working group for the calculation of the limit fund, the drafting of technical specifications and the argumentation of the needs for the procurement procedures with objects 'Maintenance of large medical materials of the manufacturer Philips / or equivalent, manufacturers Siemens / or equivalent and manufacturers Toshiba / or equivalent' for 24 months", as well as the letter of the Ministry of Education and Culture with no. 541/14 prot., dated 12.06.2023, administered at QSU "Mother Teresa" with no. 1232 prot., dated 13/06/2023 "The right to perform procurement procedures is delegated",* where as for equipment from other manufacturers, the CA must continue with the procurement procedure, in accordance with Article 41 of DCM No. 285, dated 19.05.2021 "For the Approval of Public Procurement Rules", amended, in which we find that: 1. In procurement procedures for goods, the contracting authority/entity foresees the quantity of goods that it will procure, as and the goods delivery schedule.

PROCUREMENT UNIT:

1. **Rigers Haxhiaj** — **Director/Directorate of IT and Clinical Engineering**
2. **Orald Mestani** — **Economist/French PAI**
3. **Erjona Kosta** — **Procurement Specialist/Sector**