Albania-Tirana: Medical consumables 2023/S 122-385356

Contract notice

Supplies

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority

1.1) Name and addresses

Official name: Mother Theresa University Hospital Centre

National registration number: J61911026A

Town: Tirana

NUTS code: AL022 Tiranë

Country: Albania

E-mail:

Internet address(es):

Main address:

1.3) Communication

The procurement documents are available for unrestricted and full direct access, Additional information can be obtained from the abovementioned address Tenders or requests to participate must be submitted to the abovementioned address

1.4) Type of the contracting authority

Other type: Mother Theresa University Hospital Centre, institution of dependence

1.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title:

Specific materials for the Hemodynamics service at MTUHC for 24 months, divided into lots Reference number: REF-73285-06-21-2023

II.1.2) Main CPV code

33140000 Medical consumables

II.1.3) Type of contract

Supplies

II.1.4) Short description:

Specific materials for the Hemodynamics service at MTUHC for 24 months, divided into lots (Expected Value of Contracts, for all lots): 207,998,165 (two hundred seven million nine hundred ninety eight thousand one hundred sixty five) ALL without VAT, converted into Euro according to the exchange rate of

21.06.2023: 1 947 913.14 (one million nine hundred forty seven thousand nine hundred thirteen point fourteen) euros without VAT.

Sum of prices per unit (in total for all lots): 5 499 988.00 (five million four hundred and ninety-nine thousand nine hundred and eighty-eight) ALL without VAT, converted into Euro according to the exchange rate of 21.06.2023: 51 507.66 (fifty one thousand five hundred seven point sixty six) euros without VAT.

REF-73285-06-21-2023

LOT 1 - "ICD-VR"

LOT 2 - MRI IPG FOR PHYSIOLOGICAL PACING

LOT 3 - BIVENTRICULAR PACEMAKER (CRT-P)

LOT 4 - "PACEMAKER MRI COMPATIBLE"

LOT 5 - "STENTS FOR RENAL AND CAROTIS"

II.1.5) Estimated total value

II.1.6) Information about lots

This contract is divided into lots: yes Tenders may be submitted for all lots

II.2) Description

II.2.1) **Title:**

LOT 1 - "ICD-VR" Lot No: 1

201110. 1

II.2.2) Additional CPV code(s)

33140000 Medical consumables

II.2.3) Place of performance

NUTS code: AL Shqipëria

Main site or place of performance:

Tirana, Mother Teresa University Hospital Centre

II.2.4) Description of the procurement:

No. Description of the item Unit Quantity

1 ICD VR - Single chamber implantable defibrillator with defibrilation lead 7 F, Peelable Percutaneous Lead Introducer and technical support during implantation. 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 parametrs 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, diagnostic features: episodes, markers and EMG Defibrillation lead, steroid, active fixation, with 2 defibrillation coils, choice of different length, Sheeth introducer peel away for introducing electrode (including guide wire, syringe, dilator, nedle and introducer) pcs 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 implanatation.(ICD-DR - defribillator kardiak I implantueshem, dydhomesh implantable defibrillator, me sonden ventrikulare dhe atriale kompatibile s idhe me 2 sheath (9 dhe 8 french) si dhe support teknik gjate implantimit) ICD DR dual chamber implantable defibrillator with compatible defibrillation lead with the charachteristic: Maximum delivered energy for HV therapy not less than 35 J for all shocks, Arrhythmia detection zones (VT, FVT and VF), ATP therapy delivered before and during the capacitor charging, Automatic pacing mode switch from AAJ(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. pcs 20

3 PPEEL WAY pcs 100

4 Pacing system analyser (PSA) restiriliable patient cable compatible with programer pcs 20

5 Paper for programmer pcs 10

II.2.5) Award criteria

Criteria below

Price

II.2.6) Estimated value

Value excluding VAT: 37 450 000.00 ALL

II.2.7) Duration of the contract, framework agreement or dynamic purchasing system

Duration in months: 24

This contract is subject to renewal: no

II.2.10) Information about variants

Variants will be accepted: no

II.2.11) Information about options

Options: no

II.2.13) Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds: no

II.2.14) Additional information

II.2) Description

II.2.1) **Title:**

Lot 2 "MRI IPG for physiological pacing"

Lot No: 2

II.2.2) Additional CPV code(s)

33140000 Medical consumables

II.2.3) Place of performance

NUTS code: AL Shqipëria

II.2.4) Description of the procurement:

No. Description of the item Unit Quantity

1 Pacemaker VVIR-rate adaptive implantable pulse generator with technology that allows safe MRI imaging for the patient in the magnetic fileds of 1.5 T and 3 T + indipendent programming of frequency adaptability for the zone of normal and for the zone of high physical load + automatic recognition of the moment of implantation and polarity of the electrode + automatic reprogramming of the stimulation polarity and sensing polarity + ventricular pacing lead with active or passive fixation. pcs 270

2 Pacemaker DDDR- atrio-ventricular rate adaptive impantable pulse generator with technology that allows safe MRI imaging for the patients in the magnetic fields of 1.5 T dhe 3 T+ automatic adjustment of stimulation voltage depending on the maesured pacing threshold + automatic adjustment of sensitivity in both heart chambers + algorithm for extension of AV delay for minimisation of venticular pacing + ("rate drop response" algorithm for recognition and therapy of vasovagal syncope) + independent programming of frequency adaptability for the zone of normal and for the zone of high physical load + trend of electrode impedance + recording of intracadiac

electrograms + switching from bipolar to unipolar stimulation in case the pacing impedance is outside the set values + atrial and ventricular pacing leads with active or passive fixation. pcs 120

3 Pacemaker VVIR MRI with active leds 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. Steroide eluting ventricular pacing lead wich 50 % are active fixation and 50 % are with passive fixation. Antibiotic antibacterial envelope for impantable devices designed to reduce the risk of infection. + possibility of full body absorbion + elution of minocycline and rifampicine + possibility of multiple envelope size choice. pcs 15 4 Pacemaker DDDR MRI with corresponding active leads with Antibiotic antibacterial envelope for implantable devices designed to reduce the risk of infection. Dual chamber pacemaker rate responsible with: automatic active capture control in atrium and ventricle depending on measured pacing threshold, programmable pacing polarity (unipolar and bipolar), amplitude threshold test, 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 multile envelope size choice. pcs 5

5 Sheeth-introducer peel way for introducing permanent pacemaker electrode (including guide wire, syringe, dilator, needle and introducer) 8 F. pcs 450

6 Electrodes for temporary pacing with external pacemaker 5 or 6 F. pcs 50

7 Paper for programer. pcs 10

8 Disposable large aligator clip style extension with safe connect used for temporary pacing procedures/ resterilized. pcs 10

9 External pacemaker single chamber. pcs 1

10 Pacing system analyser (PSA) restiriliable patients cable compatible with programer. pcs 20

11 Lumenless lead for stimulation of HIS bundle + electrode body diameter 4.1 Fr. + multiple lengths + technology that allows safe MRI imaging for the patient in the magnetic fields of 1.5 T and 3 T. pcs 8

12 Catheter for HIS bundle electrode placement and fixation with fixed curved. Possibility to select different curves and catheter lengths. pcs 8

13 Deflectable cathet

II.2.5) Award criteria

Criteria below

Price

II.2.6) Estimated value

Value excluding VAT: 73 668 915.00 ALL

II.2.7) Duration of the contract, framework agreement or dynamic purchasing system

Duration in months: 24

This contract is subject to renewal: no

II.2.10) Information about variants

Variants will be accepted: no

II.2.11) Information about options

Options: no

II.2.13) Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds: no

II.2.14) Additional information

II.2) Description

II.2.1) **Title:**

LOT 3 - BIVENTRICULAR PACEMAKER (CRT-P)

Lot No: 3

II.2.2) Additional CPV code(s)

33140000 Medical consumables

II.2.3) Place of performance

NUTS code: AL Shqipëria

II.2.4) **Description of the procurement:**

No. Description of the item Unit Quantity

1 Biventricular pacemaker (CRT-P) Compund 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 supression 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 ventrikular pacing lead with active fixation, 4-Bipolar steroid eluting lead for left ventricle stimulation through coronary sinus. Implantation over the wire, possibilty of choice of different distal end curves 5-Catheter for LV introduction into coronary sinus, possibilty of choice of different distal end curves.6- Accesory 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 Sheeth-introducer peel away for introducing electrode (including guide wire, syringe, dilator, needle and introducer), 2 size 7-8 F, one size 9 F. Pcs 50 2 Biventricular defribilator(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 slop, 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 of battery depletion or any other condition Biventricular defribilator(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 slop, 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 of battery depletion or any other condition. pcs 20

- 3 Subselection catheter for LV Lead introduction into target vein with angled distal Pcs 40
- 4 Pacing system analyser (PSA) restiriliable patient cable compatible with programer Pcs 10
- 5 Paper for programer Pcs 20
- 6 left ventricular lead, dif

II.2.5) Award criteria

Criteria below

Price

II.2.6) Estimated value

Value excluding VAT: 41 964 000.00 ALL

II.2.7) Duration of the contract, framework agreement or dynamic purchasing system

Duration in months: 24

This contract is subject to renewal: no

II.2.10) Information about variants

Variants will be accepted: no

II.2.11) Information about options

Options: no

II.2.13) Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds: no

II.2.14) Additional information

II.2) Description

II.2.1) **Title:**

LOT 4 "PACEMAKER MRI COMPATIBLE"

Lot No: 4

II.2.2) Additional CPV code(s)

33140000 Medical consumables

II.2.3) Place of performance

NUTS code: AL Shqipëria

II.2.4) **Description of the procurement:**

No. Description of the item Unit Quantity

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.Sheeth-introducer peel away for introducing permanent pacemaker electrode (including guide wire, syringe, dilator, needle and introducer) of standard size from minimum 7 F. pcs 145

1.1. Introducer pcs 350

2 DDDR pacemaker with atrial and ventrikular 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 atriala and pacing lead with active or passive fixation with minimum introducer of 7F. pcs 100

3 Pacing system analyser (PSA) restiriliable patients cable compatible with programmer pcs 20

4 Paper for programer pcs 20

5 Disposable large aligator clip style extension with safe connect used for tempory pacing procedures/ resterilized) pcs 20

11.2.5) **Award criteria**

Criteria below

Price

11.2.6) **Estimated value**

Value excluding VAT: 36 283 000.00 ALL

11.2.7) Duration of the contract, framework agreement or dynamic purchasing system

Duration in months: 24

This contract is subject to renewal: no

II.2.10) Information about variants

Variants will be accepted: no

II.2.11) Information about options

Options: no

II.2.13) **Information about European Union funds**

The procurement is related to a project and/or programme financed by European Union funds: no

II.2.14) **Additional information**

11.2) **Description**

II.2.1) Title:

LOT 5 "STENTS FOR RENAL AND CAROTIS"

Lot No: 5

11.2.2) Additional CPV code(s)

33140000 Medical consumables

11.2.3) Place of performance

NUTS code: AL Shqipëria

11.2.4) **Description of the procurement:**

- No. Description of the item Unit Quantity
- $1\,4.0\,x\,12-15$ 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. pcs 1
- $2\,4.0\,x\,16-19$ 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. Pcs 1
- $3\,5.0\,\mathrm{x}\,12-15\,\mathrm{mm}$ 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. Pcs 1
- $4\,5.0\,x\,16-19$ 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. Pcs 1
- $5 6.0 8 \times 14 16$ 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. Pcs 2
- $67.0 8.0 \times 15 16$ 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. pcs 1
- $7.0-8.0 \times 18-20$ 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. Pcs 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. Pcs 20
- $9\,^37.0-^39.0\,\mathrm{x}$ 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. Pcs 25 $10\,5.0-6.0\,\mathrm{x}$ 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. Pcs 5
- $11\ 7.0-8.0\ x\ 40$ 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. Pcs 10 $12\ ^39.0-10\ x\ 40$ 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. pcs 10 $13\ 3.5-5.5$ 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. pcs 40
- 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 thrugh a 7F or less introducer , FDA and CE approved indication for embolic protection during carotid artery stenting. Pcs 40
- 15~4.0~x~20~mm PTA balloon, rapid exchange delivery over .014" guidewire, 100-150~cm length, FDA or CE approval. Pcs 10
- $16\,5.0\,x\,20\,$ mm PTA balloon, rapid exchange delivery over .014" or.018" guidewire, $100-150\,$ cm length, FDA or CE approval. Pcs $30\,$
- $17.6.0 \times 20 \text{ mm}$ PTA balloon, rapid exchange delivery over .014" or .018" guidewire, 100 150 cm length, FDA or CE approval. Pcs 30

 $18\ 7.0\ x\ 20\ mm$ PTA balloon, rapid exchange delivery over .014" or .018" guidewire, $100-150\ cm$ length, FDA or CE approval. Pcs 25

19 40 – 60 cm, 6F – 7F hydrophilic guiding s

II.2.5) Award criteria

Criteria below

Price

II.2.6) Estimated value

Value excluding VAT: 18 632 250.00 ALL

II.2.7) Duration of the contract, framework agreement or dynamic purchasing system

Duration in months: 24

This contract is subject to renewal: no

II.2.10) Information about variants

Variants will be accepted: no

II.2.11) Information about options

Options: no

II.2.13) Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds: no

II.2.14) Additional information

Section IV: Procedure

IV.1) Description

IV.1.1) Type of procedure

Open procedure

IV.1.3) Information about a framework agreement or a dynamic purchasing system

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: no

IV.2) Administrative information

IV.2.2) Time limit for receipt of tenders or requests to participate

Date: 24/07/2023 Local time: 10:00

IV.2.3) Estimated date of dispatch of invitations to tender or to participate to selected candidates

IV.2.4) Languages in which tenders or requests to participate may be submitted:

English

IV.2.7) Conditions for opening of tenders

Date: 24/07/2023 Local time: 10:00

Section VI: Complementary information

VI.1) Information about recurrence

This is a recurrent procurement: no

VI.3) Additional information:

VI.4) Procedures for review

VI.4.1) Review body

Official name: Mother Theresa University Hospital Centre

Town: Tirana Country: Albania

VI.5) Date of dispatch of this notice:

23/06/2023