Item 1	NUSS OPERATIVE SET	Qty. (1)

IMPORTANT NOTE:

Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below

TECHNICAL SPECIFICATIONS:
The unit must meet or exceed the requirements listed in the table below.

Product Details	
Name of Manufacturer	
Model/ catalogue number	
Country of Origin for the offered model	
Country where the manufacturer is based	
Delivery time	
Full warranty period	
FDA clearance OR CE Mark	

	Minimum Requirements	Compliance (Y/N), Notes	*Brochure Page No.*
A	**All materials should be Certified Human Implants to be used for Surgical Treatment of Chest Deformities Pectus Excavatum and Pectus Carinatum in NUSS procedure.**		
B	**All materials should be made of Certified Grade 2 Titanium, Grade 5 Titanium and Stainless Steel.** **Only Templates made of Aluminium.**		
C	**NUSS OPERATIVE SETis required to comprise the following items and to conform to the minimal specifications outlined for each item:**		
	1. **STABILIZATION PLATE, SIZE 60MM X 16.5MM, TITANIUM.QTY (4)**		
	2. **STABILIZATION FIXATION SCREW FOR PLATE, TITANIUM. QTY (8)**		
	3. **STABILIZATION ROD 8 INCH - 203MM, TITANIUM. QTY(1)**		

	Minimum Requirements	Compliance (Y/N), Notes	*Brochure Page No.*
	4. STABILIZATION ROD 9 INCH - 229MM, TITANIUM. QTY(1)		
	5. STABILIZATION ROD 10 INCH - 254MM, TITANIUM. QTY(1)		
	6. STABILIZATION ROD 11 INCH - 280MM, TITANIUM.QTY(1)		
	7. STABILIZATION ROD 12 INCH - 305MM, TITANIUM.QTY(1)		
	8. STABILIZATION ROD 13 INCH - 330MM, TITANIUM.QTY(1)		
	9. STABILIZATION ROD 14 INCH - 355MM, TITANIUM.QTY(1)		
	10. TITANIUM WIRE Ø1.2MM X 10 METER.QTY(1)		
	11. ALUMINIUM TEMPLATE FOR STABILIZATION ROD 8 INCH - 203MM.QTY(1)		
	12. ALUMINIUM TEMPLATE FOR STABILIZATION ROD 9 INCH - 229MM.QTY(1)		
	13. ALUMINIUM TEMPLATE FOR STABILIZATION ROD 10 INCH - 254MM.QTY(1)		
	14. ALUMINIUM TEMPLATE FOR STABILIZATION ROD 11 INCH - 280MM.QTY(1)		
	15. ALUMINIUM TEMPLATE FOR STABILIZATION ROD 12 INCH - 305MM.QTY(1)		
	16. ALUMINIUM TEMPLATE FOR STABILIZATION ROD 13 INCH - 330MM.QTY(1)		
	17. ALUMINIUM TEMPLATE FOR STABILIZATION ROD 14 INCH - 355MM.QTY(1)		
	18. STABILIZATION PLATE HOLDER.QTY(1)		
	19. STABILIZATION SWORD QTY(1)		

	Minimum Requirements	Compliance (Y/N), Notes	*Brochure Page No.*
	20. STABILIZATION SCREWDRIVER WITH TORQUEMETER. QTY(1)		
	21. STABILIZATION FLIPPER. QTY(1)		
	22. MCSUTURE - DESCHAMPS LIGATURE NEEDLE 21CM/8¼", SHARP, RIGHT. QTY(1)		
	23. MCSUTURE - DESCHAMPS LIGATURE NEEDLE 21CM/8¼", SHARP, LEFT. QTY(1)		
	24. MAYO HEGAR NEEDLEHOLD.QTY(1)		
	25. METZENBAUM FINO SCISS. STR. 20CM/8". QTY(1)		
	26. METZENBAUM FINO SCISS. CVD. 18CM/7". QTY(1)		
	27. LANGENBECK RETR. 21CM/8¼" 30X11 MM. QTY(1)		
	28. WIRE CUTTING PLIER 18CM/7", CURVED, DOUBLE ARTICULATED, HARD WIRES UP TO Ø 2,2MM, SOFT WIRES UP TO Ø 2,8MM. QTY(1)		
	29. UNIVERSAL ROD BENDER UP TO Ø7MM 28.5CM. QTY(1)		
	30. PERFORATED STAINLESS STEEL BASKET - WITHOUT LID FOR EXTRA LONG CONTAINER DIM: 665X253X80MM. QTY(1)		
	31. PERFORATED STAINLESS STEEL BASKET LID ONLY FOR EXTRA LONG CONTAINER DIM:671*259MM. QTY(1)		
	32. SILICONE FIXATION SYSTEM (RAIL+SILICONE HOLDER) DIM: 240X45MM. QTY(1)		
	33. IMPLANTS HOLDING TEFLON TRAY. QTY(1)		
	34. LID PERFORATED - RED EXTRA LONG SIZE - STANDARD PLUS LINE DIM: 710X285MM. QTY(1)		
	35. BOTTOM - NON-PERFORATED FOR EXTRA LONG CONTAINER OUTSIDE DIM: 725X272X192MM (INNER DIM: 670X260X185MM). QTY(1)		

- **Offers not complying with any of the special terms or the technical specifications shall be considered non-conforming with tender requirements.**

- **Any vendor providing FORGED documents shall be disqualified from the current tender and banned from participating in any future RMS tenders**

- **Offers submitted by vendors with previously complaints or unsolved issues will be excluded from the current tender**

1. The vendor is responsible to ensure through official documents that classified medical instrument are manufactured in conformity with applicable quality system standards (ISO) and must provide the latest copy of the certificates of the following standards formally endorsed by the chamber of commerce of the manufacturing origin with the technical offer:

A- ISO 13485:2016

Medical devices — Quality management systems — Requirements for regulatory purposes

ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

B- ISO 9001:2015

Quality management systems — Requirements

specifies requirements for a quality management system aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

C- ISO 7153-1:2016

Surgical instruments — Materials — Part 1: Metals

specifies metals commonly used to manufacture various types of standard surgical instruments, including but not limited to those used in general surgery, orthopaedics and dentistry.

D- ISO 7151:1988

Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods

Specification of basic requirements for as well physical characteristics as workmanship, of the steel grades used and heat treatment of component parts, excluding rivets, screws and parts manufactured of material grade M.

E- ISO 7740:1985

Instruments for surgery — Scalpels with detachable blades — Fitting dimensions

Lays down the dimensions of two sizes of fitting features for detacheable scalpel blades and the handles with which they are used. It secures a good fitting and interchangeability of detachable blades for scalpels manufactured in different countries or by different manufacturers

F- ISO 7741:1986

Instruments for surgery — Scissors and shears — General requirements and test methods

This standard deals with materials, heat treatment and hardness of component parts, corrosion resistance, workmanship and cutting ability of scissors and shears used in the surgery and defines the test methods.

G- ISO 13402:1995

Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure

Describes test methods to determine the resistance of stainless steel surgical and dental hand instruments against autoclaving, corrosion and thermal exposure.

2. **Offered items should be from reputable well known manufacturers and excellent experience in the field previously evaluated and accepted in Main Hospitals at Royal Medical Service. Bidder must submit samples with the technical offer from each brand that was submitted in the offer to be assessed and /or evaluated by RMS**
   - **A. Offers which do not include such samples will be considered non-conforming.**
   - **B. Offers which fail the evaluation/assessment process will be excluded from the tender.**
   - **C. Samples will be returned to the Bidder at the end of the evaluation/assessment process except for samples from Bidders winning the final award where they will be the property of RMS and will be kept as a reference for the receiving committee.**
   - **D. The purchasing committee has the right to require a sample for any instrument previously installed in RMS Hospitals.**

3. **A. Bidder is not allowed to submit more than one offer for the same item whether that's solely or in coalition or partnership with other bidders.**
   B. Bidder is allowed to include within their offer optional alternatives for the same offered item from the same manufacturer.

4. **Required certificates:**
   - **A. For instruments of USA origin, a copy of a certificate of FDA approval must be submitted with the technical offer.**

B. For instruments of other origins, a copy of either a CE certificate (MDD)/TUV OR a certificate of FDA approval must be submitted with the technical offer.

C. With each offer, bidders must provide a formally endorsed document issued by the manufacturer stating that the bidder is the authorized agent/ distributor for the offered item.

D. In all of the above cases (except C) certificates must be formally endorsed by JFDA .

E. Any vendor not submitting all required certificates will be eliminated.

5. All Offered items should be supplied with free sale certificate said confirmation should be stating clearly that the item is freely sold in the country of origin .

6. All items should be engraved or etched with manufacturing origin ,company logo and code number .

7. Each instrument set will be awarded as a listed set which including its specific sterilization baskets and trays .

8. Bidders must submit their reservations/queries regarding tender specifications and/or special terms within the first third of the tender closing period starting from the tender announcement date. Reservations/queries submitted after the end of this period will be rejected

9. The supplier must furnish DRMS with a guarantee letter stamped and legalized by the Notary Public equals to (115%) of the total value of the awarded equipment valid for (24) months from the date of final acceptance of the instruments by DRMS which shall cover rusting, manufacturing defects, wear and tear and corrosion.

10. Offers must include clear original catalogues for all offered items. Images and part numbers of offered items must be provided, highlighted and outlined clearly.

11. Offers must include fully detailed information as a soft copy (either Microsoft office or Microsoft excel format) in addition to a hard copy , mentioning the exact model/catalogue number and country of origin of the offered item(s), full description/specifications.And any accessories or options included in the offer.

12. Official website of the manufacturer must be provided. The website must clearly demonstrate the history profile and manufacturing features of the company.
13. Any complementary parts , accessories and consumable items necessary for the proper operation of surgical Instruments must be included in the offer , priced separately and to be be approved by the manufacturer.
14. A. complementary parts availability must be guaranteed and can be purchased without the need replace the entire system of surgical instruments
    B. Bidder will bear any responsibility resulting from the awarding of insufficient items or sub-items.
15. Pricing must include services of sale, shipment, transportation, delivery from port to site or to Main Medical Stores.
16. A. custom clearance of goods shall be the responsibility of the Jordanian Armed Forces (JAF), however, suppliers shall bear all costs incurred by handling charges and any demurrage charges or extra expenses incurred by the port's corporation (including expenses caused by delay in presenting the necessary shipment documents for either clearing or transporting the goods to the required location mentioned in the final order, delivery note issuing charges, unloading charges, local shipping charges etc.).
    B.The supplier is also responsible for providing of all relevant shipping documents, together with the delivery order(s).
17. Delivery period should be mentioned clearly; the purchasing committee has the right to reject any offer with delivery time exceeding 4 months.
18. Goods are to be brand new; manufacturing date of the delivered products should not exceed 18 months from the date of the final award.
19. A. DRMS has the right to increase the awarded quantities by a percentage not exceeding 35% after the final order notification with the same prices, terms and conditions of the original contract upon DRMS request and approval of the awarded party.
    B. DRMS has the right to decrease the awarded quantities by a percentage not exceeding 50% after the final order notification with the same prices, terms and conditions of the original contract upon DRMS request and approval of the awarded party.

20. For offers submitted in Jordanian dinars, payment will be either by wire transfer or by cheque after final acceptance of goods, Any other way of payment will be rejected .