



Bid Document/ बिड दस्तावेज़

Bid Details/बिड विवरण		
Bid End Date/Time/बिड बंद होने की तारीख/समय	21-01-2025 16:00:00	
Bid Opening Date/Time/बिड खुलने की तारीख/समय	21-01-2025 16:30:00	
Bid Offer Validity (From End Date)/बिड पेशकश वैधता (बंद होने की तारीख से)	180 (Days)	
Ministry/State Name/मंत्रालय/राज्य का नाम	Odisha	
Department Name/विभाग का नाम	Labour And Employees State Insurance Department Odisha	
Organisation Name/संगठन का नाम	Director Of Esi Scheme,bhubaneswar	
Office Name/कार्यालय का नाम	Bhubaneswar	
क्रेता ईमेल/Buyer Email	store-supdt@gov.in	
Total Quantity/कुल मात्र	1	
ltem Category/मद केटेगरी	Arthroscopy System (V2) (Q2)	
Minimum Average Annual Turnover of the bidder (For 3 Years)/बिडर का न्यूनतम औसत वार्षिक टर्नओवर (3 वर्षों का)	42 Lakh (s)	
OEM Average Turnover (Last 3 Years)/मूल उपकरण निर्माता का औसत टर्नओवर (गत 3 वर्षों का)	320 Lakh (s)	
Years of Past Experience Required for same/similar service/उन्हीं/समान सेवाओं के लिए अपेक्षित विगत अनुभव के वर्ष		
MSE Exemption for Years of Experience and Turnover/ अनुभव के वर्षों से एमएसई छूट	No	
Startup Exemption for Years of Experience and Turnover/ अनुभव के वर्षों से स्टार्टअप छूट	No	

Bid Details/बिड विवरण		
Document required from seller/विक्रेता से मांगे गए दस्तावेज़	Experience Criteria, Past Performance, Bidder Turnover, Certificate (Requested in ATC), OEM Authorization Certificate, OEM Annual Turnover, Additional Doc 1 (Requested in ATC), Additional Doc 2 (Requested in ATC), Additional Doc 3 (Requested in ATC), Additional Doc 4 (Requested in ATC), Compliance of BoQ specification and supporting document *In case any bidder is seeking exemption from Experience / Turnover Criteria, the supporting documents to prove his eligibility for exemption must be uploaded for evaluation by the buyer	
Do you want to show documents uploaded by bidders to all bidders participated in bid?/	No	
Past Performance/विगत प्रदर्शन	80 %	
Bid to RA enabled/बिड से रिवर्स नीलामी सक्रिय किया	Yes	
RA Qualification Rule	H1-Highest Priced Bid Elimination	
Type of Bid/बिड का प्रकार	Two Packet Bid	
Time allowed for Technical Clarifications during technical evaluation/तकनीकी मूल्यांकन के दौरान तकनीकी स्पष्टीकरण हेतु अनुमत समय	2 Days	
Inspection Required (By Empanelled Inspection Authority / Agencies pre- registered with GeM)	No	
Evaluation Method/मूल्यांकन पद्धति	Total value wise evaluation	
Arbitration Clause	No	
Mediation Clause	No	

EMD Detail/ईएमडी विवरण

Advisory Bank/एडवाईजरी बैंक	State Bank of India
EMD Amount/ईएमडी राशि	240000

ePBG Detail/ईपीबीजी विवरण

Advisory Bank/एडवाइजरी बैंक	State Bank of India
ePBG Percentage(%)/ईपीबीजी प्रतिशत (%)	5.00
Duration of ePBG required (Months)/ईपीबीजी की अपेक्षित अवधि (महीने).	38

(a). EMD EXEMPTION: The bidder seeking EMD exemption, must submit the valid supporting document for the

relevant category as per GeM GTC with the bid. Under MSE category, only manufacturers for goods and Service Providers for Services are eligible for exemption from EMD. Traders are excluded from the purview of this Policy./जेम की शर्तों के अनुसार ईएमडी छूट के इच्छुक बिडर को संबंधित केटेगरी के लिए बिड के साथ वैध समर्थित दस्तावेज़ प्रस्तुत करने है। एमएसई केटेगरी के अंतर्गत केवल वस्तुओं के लिए विनिर्माता तथा सेवाओं के लिए सेवा प्रदाता ईएमडी से छूट के पात्र हैं। व्यापारियों को इस नीति के दायरे से बाहर रखा गया है।

(b). EMD & Performance security should be in favour of Beneficiary, wherever it is applicable./ईएमडी और संपादन जमानत राशि, जहां यह लागू होती है, लाभार्थी के पक्ष में होनी चाहिए।

Beneficiary/लाभार्थी :

DIRECTOR

Bhubaneswar, Labour and Employees State Insurance Department Odisha, Director of ESI Scheme, Bhubaneswar, (Director Of Esi Scheme)

MSE Purchase Preference/एमएसई खरीद वरीयता

MSE Purchase Preference/एमएसई खरीद वरीयता	No

MII Purchase Preference/एमआईआई खरीद वरीयता

MII Purchase Preference/एमआईआई खरीद वरीयता	No	
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1. The minimum average annual financial turnover of the bidder during the last three years, ending on 31st March of the previous financial year, should be as indicated above in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the bidder is less than 3-year-old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.

2. Experience Criteria: In respect of the filter applied for experience criteria, the Bidder or its OEM {themselves or through reseller(s)} should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Organization / PSU for number of Financial years as indicated above in the bid document before the bid opening date. Copies of relevant contracts to be submitted along with bid in support of having supplied some quantity during each of the Financial year. In case of bunch bids, the category of primary product having highest value should meet this criterion.

3. OEM Turn Over Criteria: The minimum average annual financial turnover of the OEM of the offered product during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.

4. Past Performance: The Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar Category Products for 80% of bid quantity, in at least one of the last three Financial years before the bid opening date to any Central / State Govt Organization / PSU. Copies of relevant contracts (proving supply of cumulative order quantity in any one financial year) to be submitted along with bid in support of quantity supplied in the relevant Financial year. In case of bunch bids, the category related to primary product having highest bid value should meet this criterion.

5. Reverse Auction would be conducted amongst all the technically qualified bidders except the Highest quoting bidder. The technically qualified Highest Quoting bidder will not be allowed to participate in RA. However, H-1 will also be allowed to participate in RA in following cases:

- i. If number of technically qualified bidders are only 2 or 3.
- ii. If Buyer has chosen to split the bid amongst N sellers, and H1 bid is coming within N.
- iii. In case Primary product of only one OEM is left in contention for participation in RA on elimination of H-1.
- iv. If L-1 is non-MSE and H-1 is eligible MSE and H-1 price is coming within price band of 15% of Non-MSE L-1
- v. If L-1 is non-MII and H-1 is eligible MII and H-1 price is coming within price band of 20% of Non-MII L-1

Arthroscopy System (V2) (1 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के लिए आवश्यक (Allowed Values)/अनुमत मूल्य
GENERAL	Product Description	Arthroscopy System
	Components of the Arthroscopy system to be from the same OEM	Arthroscope, Camera console, Light source & cable
ARTHROSCOPE	Autoclavable Telescope	Yes
	Number of Arthroscope	2
	Field of view	Wide angle
	Angle of view (degree)	30°, 70°
	Usage	Knee, Shoulder, Elbow, Ankle, Hip, Wrist, Small Joints
	Diameter (mm)	3.5 to 4
	Length (cm)	16 to 20
	Fibre Optic light transmission incorporated	Yes
	Standard Ocular window for coupling camera head	Yes
	Arthroscope sheath, rotatable	Yes
	Sheath diameter and working Length compatible with scope	Yes
	Scratch resistant saphire lens on proximal and distal tip	Yes
	Rod lens systems for optimum brightness, contrast	Yes
	Two rotatable stopcocks	Yes
	Autoclavable stopcocks	Yes
	Semi sharp obturator compatible with arthroscopy sheath	Yes
	The surface of the arthroscope shall be free of pores, cracks, and remainders of tooling agents	Yes
CAMERA CONSOLE	Camera processor	2D
SYSTEM	Video Camera type	4K (3840x 2160)
	Zoom lens facility available	Yes

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के लिए आवश्यक (Allowed Values)/अनुमत मूल्य
	The console interface is menu- driven with the facility for programmable individual surgeon preferences	Yes
	System has facility for numerous Display, Input & Output ports	Yes
	USB for Digital Recording	Yes
	Compatible Video output	Minimum 2 video output
	Progressive Scan technology	Yes
	Consistent use of 16:9 format for input & Output to guarantee genuine resolution	Yes
	Optimization of image quality & Digital Source sampling for maximizing hi-fidelity image transmission by image sensor	Yes
	Image sensor	CCD/CMOS
	Provision of near/close focus observation available	Yes
	The system automatically optimizes all settings, The system is ready-to-use as soon as it is connected to the camera control unit	Yes
IGHT SOURCE &	Light Source Type	LED Lamp
ABLE	Lamp life	20000 hours or more
	Colour temperature of light source (Approx)	5500 K to 6500 K
	Minimum LED Lamp intensity	1500 lumens or more
	High visual and photographic clarity for color retention due to high color temperature that corresponds to the brightness of sunlight	Yes
	Monitoring of lamp function	Yes
	Means of light intensity adjustment facility	Continuously adjustable from 0 to100% manually/automatically
	Fiber Optic cables autoclavable	Yes
	Minimum Thickness of Fiber Optic Cable (mm)	3.5 mm
	Minimum Length of Fiber Optic Cable (cm)	230 cm

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के लिए आवश्यक (Allowed Values)/अनुमत मूल्य
	Provision of backlit front panel indicator	Yes
DISPLAY MONITOR	Monitor view	2D
	Medical grade monitor is compatible with Camera system	Yes
	Monitor resolution	4K (3840x 2160)
	Monitor Display	LED/Backlit LED
	Size of Monitor (inch)	26 to 30
	Minimum Video input ports as per monitor resolution	2
	Versatile Multi-Format Signal support	Yes
	Monitor is Drip water protected with dust proof housing	Yes
	Monitor has the aspect ratio	16:9
	Item should be from same OEM make	No (Item to be sourced from reputed OEM with OEM warranty support)
DATA MANAGEMENT SYSTEM	The system is compact and provided with medical grade recording device	Yes
	Type of recording system	2D
	Provision for digital storage of still images, video sequences, and audio files format available	4K
	System is sterile, ergonomic operation via touch screen, camera head buttons / foot switch	Yes
	System has full featured Graphical User Interface DICOM capability	Yes
	Provision of Portable memory and USB slot for still image recording available	Yes
	Automatic creation of standard report possible	Yes
	Minimum internal memory	1 TB
	Live streaming facility	Yes
	Should be from same OEM make	No (Item to be sourced from reputed OEM with OEM warranty support)

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के लिए आवश्यक (Allowed Values)/अनुमत मूल्य
MOBILE VIDEO TROLLEY	Video trolley is of Shockproof powder-coated, good quality rust free material and is able to take the load of all equipment with accessories	Yes
	Video trolley has the provision of mounting positions for central-monitor- mount, articulation-monitor-arm, cable winding aid, Fluid bag holder and tubing clamp etc	Yes
	Video trolly rides in 4 antistatic dual wheels, with atleast 2 lockable castors	Yes
	One camera head mount on Video cart	Yes
	Channel inside the stand is to avoid hanging of the cables	Yes
	Integrated power board to provide connection to all units	Yes
	Minimum 4 shelves (including one extendable shelf, one with handle and drawer with lock)	Yes
	Inbuilt arm for monitor	Yes
	Video cart is provided with power column with 10x cables and equipotential bonding cable	Yes
	One adjustable swivel arm for monitor to mount either on left or onright side for touch screen	Yes
	Trolley should be from same OEM make	No (Item to be sourced from reputed OEM with OEM warranty support)
STANDARD	Camera Head (Nos.)	1
ACCESSORIES	Optical fiber light cable (Nos.)	1
	All the accessories provided are compatible with the Arthroscope and authorization certificate for compatibility by the parent company/supplier of the Arthroscope provided	Yes
ELECTRICAL REQUIREMENTS	Input Power Supply	220-240V AC, 50 HZ
CERTIFICATIONS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के लिए आवश्यक (Allowed Values)/अनुमत मूल्य
	Availability of valid Medical Device license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Certification for manufacturing unit	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rule (MDR) 2017 as amended till date	Yes
	Conformity to standards for safety	IEC/EN 60601-1 or equivalent BIS Standard
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
WARRANTY	Warranty in Years (Option of comprehensive warranty is available through bidding only, which if opted will supersede normal warranty in the catalogue)	3, 5 Or higher (year)
MISCELLANEOUS REQUIREMENTS	OEM/Reseller shall ensure uninterrupted availability of all spares, consumables for atleast 10 years	Yes
	Availability of toll free facility for technical support maintened by OEM or authorized agencies	Yes
	User/Technical/Maintenance manuals to be provided in English in hard and soft copy	Yes
	Details of equipments and procedures required for local calibration and routine maintenance to be provided and advanced maintenance task documentation also to be furnished	Yes
	Supplier to perform installation, safety and operation checks before handover	Yes
	Training of users in operation and basic maintenance shall be provided	Yes

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के लिए आवश्यक (Allowed Values)/अनुमत मूल्य
	Contact details of manufacturer, supplier and local service agent to be provided	Yes
	Certificate of calibration from the manufacturer	Yes

Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा

S.No./क्र. सं.	Consignee Reporting/Officer/ परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/मात्रा	Delivery Days/डिलीवरी के दिन
1	KANCHAN SETHY	751012,PLOT NO: A/122, UNIT - 8, NAYAPALLI, BHUBANESWAR	1	45

Special terms and conditions-Version:1 effective from 31-05-2024 for category Arthroscopy System (V2)

- All Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
 - 2. The sellers are registered on GeM based on the self declaration of valid Medical Device License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of Medical Device license, product certification, manufacturer certification/licenses, test reports etc.
 - 3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of Medical Device license held by them.
 - 4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
 - 5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.
 - 6. **Comprehensive warranty:** Comprehensive warranty shall include preventive maintenance including calibration as per technical/ service /operational manual of the manufacturer, service charges and spares. During the warranty period commencing from date of the successful completion of warranty period, Service personnel shall visit each consignee site as recommended in the manufacturer's technical/ service /operational manual, at least once in six months. warranty

shall not be including the consumables. Further there will be 98% uptime warranty during warranty period on 24 (hrs) X 7 (days) X 365 (days) basis, with penalty, to extend warranty period by double the downtime period.

- 7. Service centres: Details of Service outlets in India to render services for equipment to be furnished to buyer/consignees with complete address, telephone numbers, e mails etc at time of making the supplies. It shall be the responsibility of seller to ensure that authorized service centres are available to cater to the areas where supplies are made within reasonable distance from where the service calls can be handled. Details of toll-free numbers for service call and online registration of service requests also to be provided buyer/consignee at the time of supplies.
- 8. **Source of supply:** It shall be responsibility of seller to provide Documents regarding source of equipments such as copy of Performa invoice or any other documents to establish that the products supplied are manufactured by OEM indicated and sourced from them.
- 9. Packing and Marking: Medical equipments being very delicate and sensitive packing for the goods should be strong and durable enough to withstand transit including transhipment (if any), rough handling, open storage etc. without any damage, deterioration etc. .The size, weights and volumes of the packing cases, remoteness of the final destination of the goods, availability or otherwise of transport and handling facilities at all points during transit up to final destination,. Quality of packing, the manner of marking within & outside the packages and provision of accompanying documentation shall take into consideration the type of medical equipments being supplied. The accessories shall be suitably labelled and packed. Each of the package shall be marked on three sides with indelible paint of proper quality: indicating contract number and date, brief description of goods including quantity, Packing list reference number, country of origin of goods and any other relevant details.
- 10. **Spare Parts:** Seller shall provide materials, information etc. pertaining to spare parts manufactured and supplied by the OEM. It shall be ensured that the required spares are available for purchase at least for 10 years from date of supplies. In case due to any reasons the production of the spare parts is discontinued sufficient advance notice should be given to the buyer/consignee before such discontinuation to provide adequate time to purchase the required spare parts etc. Further, OEM and their service centres/dealers shall carry sufficient inventories to assure ex-stock supply of consumables and spares for the equipments so that the same are available. OEM or reseller shall always accord most favoured client status to the buyer/consignee and shall give the most competitive price for spares and consumables of its machines/equipments supplied.
- 11. **Installation, Training, Manuals:** Seller shall be responsible to carry out Installation & commissioning, Supervision and Demonstration of the goods. They shall provide required jigs and tools for assembly, minor civil works for the completion of the installation and Training of Consignee's representatives for operating and maintaining the equipment and supplying required number of operation & maintenance manual for the goods. In case the category parameters are specifying any requirements regarding the installations, training and manuals the same shall also be applicable.
- 12. **Electrical safety checking:** Sellers are required to make sure that they furnish the list of equipments for carrying out routine and preventive maintenance to buyer/consignee. They should make sure to periodically check the electrical safety aspects as per BIS Safety Standards or equivalent .In case they do not have required equipment for such testing should ensure that the equipments checked for electrical safety compliance through labs with facilities for such checking during every preventive maintenance call.
- 13. Software: All software updates should be provided free of cost during warranty period.

Buyer Added Bid Specific Terms and Conditions/क्रेता द्वारा जोड़ी गई बिड की विशेष शर्तें

1. Generic

OPTION CLAUSE: The Purchaser reserves the right to increase or decrease the quantity to be ordered up to 25 percent of bid quantity at the time of placement of contract. The purchaser also reserves the right to increase the ordered quantity by up to 25% of the contracted quantity during the currency of the contract at the contracted rates. Bidders are bound to accept the orders accordingly.

2. Generic

While generating invoice in GeM portal, the seller must upload scanned copy of GST invoice and the screenshot of GST portal confirming payment of GST.

3. **OEM**

IMPORTED PRODUCTS: In case of imported products, OEM or Authorized Seller of OEM should have a registered office in India to provide after sales service support in India. The certificate to this effect should be submitted.

4. Forms of EMD and PBG

Bidders can also submit the EMD with Account Payee Demand Draft in favour of

DIRECTOR OF ESI SCHEME,ODISHA, BHUBANESWAR payable at BHUBANESWAR

Bidder has to upload scanned copy / proof of the DD along with bid and has to ensure delivery of hardcopy to the Buyer within 5 days of Bid End date / Bid Opening date.

5. Scope of Supply

Scope of supply (Bid price to include all cost components) : Supply Installation Testing Commissioning of Goods and Training of operators and providing Statutory Clearances required (if any)

6. Certificates

Bidder's offer is liable to be rejected if they don't upload any of the certificates / documents sought in the Bid document, ATC and Corrigendum if any.

7. Certificates

ISO 9001: The bidder or the OEM of the offered products must have ISO 9001 certification.

8. Turnover

Bidder Turn Over Criteria: The minimum average annual financial turnover of the bidder during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the bidder is less than 3 year old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.

9. Turnover

OEM Turn Over Criteria: The minimum average annual financial turnover of the OEM of the offered product during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria. In case of bunch bids, the OEM of CATEGORY RELATED TO primary product having highest bid value should meet this criterion.

10. Service & Support

Dedicated /toll Free Telephone No. for Service Support : BIDDER/OEM must have Dedicated/toll Free Telephone No. for Service Support.

11. Warranty

Timely Servicing / rectification of defects during warranty period: After having been notified of the defects / service requirement during warranty period, Seller has to complete the required Service / Rectification within 3 days time limit. If the Seller fails to complete service / rectification with defined time limit, a penalty of 0.5% of Unit Price of the product shall be charged as penalty for each week of delay from the seller. Seller can deposit the penalty with the Buyer directly else the Buyer shall have a right to recover all such penalty amount from the Performance Security (PBG).Cumulative Penalty cannot exceed more than

10% of the total contract value after which the Buyer shall have the right to get the service / rectification done from alternate sources at the risk and cost of the Seller besides forfeiture of PBG. Seller shall be liable to re-imberse the cost of such service / rectification to the Buyer.

12. Buyer Added Bid Specific ATC

Buyer Added text based ATC clauses

Additional Clause1 (Bidder must have to comply with Buyers added ATC)

1) Tissue ablator for Arthroscopy

Technical Specifications for controlled tissue ablator for Arthroscopy Controlled ablation based o n low temperature bi-polar radio frequency technology.

Should not have any need for the secondary patient grounding pad.

Should have real time flow regulation with console.

Should have tube temperature sensing and over temperature algorithm

The output voltage settings should be controlled by regulation on the generator by simple setting from Lo w to high. Output voltage of the RF current should vary from 0-320Vrms @ 100 kHZ frequency depending on the above settings

The generator should have a feature of Automatic scope saver detection, i.e. when the probe comes too cl ose to endoscope the controller pauses radiofrequency output and resumes radiofrequency output when th e probe is returned to safe distance.

The generator should have ability to use a foot control, wired or wireless.

The generator should also have the ability to use a finger switch controlled probes. There should be ability to adjust ablation as well as coagulation with different settings

There should be compatibility for probes that are used for minimally invasive treatments of Tendons and F ascia as well as probes used for sculpting articular cartilage

The generator should be able to take different types of probes for open and minimally invasive arthroscopi c procedures

The controller should have the ability to tell the ambient temperature of the arthroscopic fluid (in the range of 20° C to 60° C) when connected with probes that have a thermocouple present near their tip.

The controller has facility to control temperature of joint without compromising time laps. The Controller s hould have ability to adopt 2 different wands at a time. The controller should have suction, no additional s uction machine needed. The Controller should have ability to store customized surgeon settings. The controller should have vac facility to clear joint in one touch.

Quality Standards:

1) The quoted model must be registered under CDSCO and submit the license to manufacture for sale or fo r distribution of the medical device.

2) The manufacturer should be EN ISO 13485 certificate issued from a notified. body or ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate is sued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA.

3) Product Quality standard: The quoted model should be USFDA 510K/ CFG) Or EU0CE certified issued Fro m a notified body)

4) Safety Standard: Electrical safety conforms to standards for electrical safety IEC60601-1

2) Arthroscopic Resection Shaver System -Qty -1

The Shaver system should comprise of Controller Console, Shaver Hand-piece, and Foot pedal.

2.1 Shaver Controller Unit The Controller console should have receptacles for both Shaver handpiece, F oot Pedal and also other powered instrumentation \cdot The console screen should capture all information pert aining to minimum, maximum and set speeds

for installed blade type; horizontal bar graph of blade speed relative to range; blade direction; diag nostic i nformation. \cdot Should provide control for momentary push switches for increasing and decreasing speed set ting. \cdot The Unit should have 2 Modes for Normal and Aggressive Resection so as to balance efficacy with sa fety. \cdot The Console should provide variable rpm ranging between 100rpm to 10,000 rpm as per the blade o r burs used. \cdot The Motor should offer Forward, Reverse and Oscillation Mode for Resection.

2.2 Shaver Hand Piece \cdot The autoclavable shaver hand piece, which is compact, lightweight and ergono mically designed, with hand control. \cdot The connecting cable should be autoclavable and replaceable with le ngth of approx. 10Ft. \cdot The hand piece should be not more than 8 Inches length and 500gms. \cdot The hand piece should have suction control lever. \cdot The Shaver Hand piece should have safety mechanism of Blade Wi ndow Lock to avoid any unintentio nal tissue damages on pull out. \cdot The Shaver hand piece should be accessible and controllable from shaver hand piece. \cdot The Shaver hand piece should have pushbutton motor controls: Forward, Reverse Oscillate, and Blade and Window Lock. \cdot Input voltage of 100 to 2 40V, 50/60 Hz power consumption not more than 350VA.

Foot Pedal – Shaver · The variable speed foot pedal should be sturdy with a long connecting cable. · The f oot pedal controls should include three standard operating modes, i.e. Forward, Reverse and Os cillation. · **Quality Standards:** · 1) The quoted model must be registered under CDSCO and submit the license to m anufacture for sale or for distribution of the medical device. · 2) The manufacturer should be EN ISO 13485 certificate issued from a notified. body or ICMED 13485 (w ith or without plus) certificate issued from certification bodies accredited by NABCB or ISO 13485 certificat e issued from certification bodies accredited by NABCB or ISO 13485 certified e issued from certification bodies accredited by NABCB or ISO 13485 certified under I AF MLA. · 3) Product Quality standard: The quoted model should be USFDA 510K/ CFG) Or EUOCE certified issued · From a notified body) · 4) Safety Stand ard: Electrical safety conforms to standards for electrical safety IEC60601-1

3) Arthroscopy Pump (Fluid Management System)- Qty-1No • Maximum flow rate of not less than 2 .5 ltr/min for procedural speed and efficiency • Should be LCD touch/Display screen are described in the pr eoperative setup and operations. • Automatic Joint pressure maintenance up to 10-150 mmHg • Flow rate should be change as per operating cannula connection • Advanced Flow Regulation for optimal flow perfor mance and pressure maintenance • Disposable tube sets for inflow/outflow (box of 3pcs). •

Quality Standards: • 1) The quoted model must be registered under CDSCO and submit the license to m anufacture for sal e or for distribution of the medical device. • 2) The manufacturer should be EN ISO 1348 5 certificate issued from a notified. body or ICMED 13485 (with or without plus) certificate issued from certi fication bodies accredited by NABCB or ISO 13485 cer tificate issued from certification bodies accredited b y NABCB / Nationally Recognized Accreditation Boa rd under IAF MLA. • 3) Product Quality standard: The q uoted model should be USFDA 510K/ CFG) Or EUOCE certified issu ed • From a notified body) • 4) Safety S tandard: Electrical safety conforms to standards for electrical safety IEC60601-1

4) Hand Instruments •

Straight Punch-2no •

Straight Probe-2no •

Tissue Grasper-2no •

Suture Retriever - 2no

Knot Pusher & Suture Cutter-2n0

The instrument steel should comply to EN ISO 7153 standard for stainless steel used for surgical instrumen ts and ISO 13402 standards: Resistance against autoclaving, corrosion and thermal exposure. Necessary c ertificate should be furnished. Stainless steel material Grade should be AISI 410 and 420 certified and sho uld be supported by test reports. Instruments should carry Laser marking indicating the Manufacturer's na me and Batch No/ Lot No/ bar cod e/ QR code, and Country of Origin. All instruments should be provided wi th 2yrs of free replacement warranty.

Additional Clause 2:

EMD Exemption as per General Terms and Conditions on submission 4.0 (Version 1.12) dt 16th August 202

3 the EMD exemptions are applicable for Local MSEs only registered in Odisha (Only manufacturer of the s ame item) with the respective DICs, Khadi, village, Cottage & Handicraft Industries, OSIC, NSIC shall be exempted from submission of EMD, subject to submission of the valid registration certificate from the conc erned authority. None of the bidders other than these categories are exempted from submission of EMD. N o n submission of EMD (Not meeting to the above-mentioned criteria) the bid shall be rejected / disqualifie d

Additional Clause 2: Bidder / Supplier /Organization/ Manufacturer /Proprietor /OEM of the (Bidder/Supplier) /ANY of the Director (s) shall not be banned or suspended or blacklisted by any Government /Public Sector Undertaking / Corporate organization or convicted in any Court of Law across India or declared Bankrupt o r insolvent. A self-declaration certificate must be uploaded in the GeM portal under Bidders Official letter H ead.

Additional Clause no.3 Both manufacturer and its authorized dealer are not allowed to participate in the sa me tender. In cases where the manufacturer has submitted the bid, the bids of its authorized dealer will n ot be considered, as per GFR manual for Procurement of Goods 2017, Chapter 5, clause 5.1.4 (viii) In case the manufacturer authorizes any bidder, then the manufacturer should provide sole authorization to only o ne bidder against this specific bid reference number

Additional Clause4:

Past Performance: The Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar Category Products for 80% of bid quantity, in last three financial years before the bid opening da te to any Central / State Govt Organization / PSU / Public Listed Company. Copies of relevant contracts (pr oving supply of cumulative order quantity in any last three financial years) to be submitted along with bid i n support of quantity supplied in the relevant financial year.

13. Generic

Bidder financial standing: The bidder should not be under liquidation, court receivership or similar proceedings, should not be bankrupt. Bidder to upload undertaking to this effect with bid.

14. Generic

End User Certificate: Wherever Bidders are insisting for End User Certificate from the Buyer, same shall be provided in Buyer's standard format only.

15. Generic

Experience Criteria: The Bidder or its OEM {themselves or through reseller(s)} should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Organization / PSU for 3 years before the bid opening date. Copies of relevant contracts to be submitted along with bid in support of having supplied some quantity during each of the year. In case of bunch bids, the primary product having highest value should meet this criterion.

16. Generic

Installation, Commissioning, Testing, Configuration, Training (if any - which ever is applicable as per scope of supply) is to be carried out by OEM / OEM Certified resource or OEM authorised Reseller.

17. Generic

Manufacturer Authorization:Wherever Authorised Distributors/service providers are submitting the bid, Authorisation Form /Certificate with OEM/Original Service Provider details such as name, designation, address, e-mail Id and Phone No. required to be furnished along with the bid

18. Generic

Without prejudice to Buyer's right to price adjustment by way of discount or any other right or remedy

available to Buyer, Buyer may terminate the Contract or any part thereof by a written notice to the Seller, if:

i) The Seller fails to comply with any material term of the Contract.

ii) The Seller informs Buyer of its inability to deliver the Material(s) or any part thereof within the stipulated Delivery Period or such inability otherwise becomes apparent.

iii) The Seller fails to deliver the Material(s) or any part thereof within the stipulated Delivery Period and/or to replace/rectify any rejected or defective Material(s) promptly.

iv) The Seller becomes bankrupt or goes into liquidation.

v) The Seller makes a general assignment for the benefit of creditors.

vi) A receiver is appointed for any substantial property owned by the Seller.

vii) The Seller has misrepresented to Buyer, acting on which misrepresentation Buyer has placed the Purchase Order on the Seller.

19. Certificates

The bidder is required to upload, along with the bid, all relevant certificates such as BIS licence, type test certificate, approval certificates and other certificates as prescribed in the Product Specification given in the bid document.

20. Service & Support

Escalation Matrix For Service Support : Bidder/OEM must provide Escalation Matrix of Telephone Numbers for Service Support.

21. Warranty

Warranty period of the supplied products shall be 3 years from the date of final acceptance of goods or after completion of installation, commissioning & testing of goods (if included in the scope of supply), at consignee location. OEM Warranty certificates must be submitted by Successful Bidder at the time of delivery of Goods. The seller should guarantee the rectification of goods in case of any break down during the guarantee period. Seller should have well established Installation, Commissioning, Training, Troubleshooting and Maintenance Service group in INDIA for attending the after sales service. Details of Service Centres near consignee destinations are to be uploaded along with the bid.

22. Warranty

Successful bidder will have to ensure that adequate number of dedicated technical service personals / engineers are designated / deployed for attending to the Service Request in a time bound manner and for ensuring Timely Servicing / rectification of defects during warranty period, as per Service level agreement indicated in the relevant clause of the bid.

Disclaimer/अस्वीकरण

The additional terms and conditions have been incorporated by the Buyer after approval of the Competent Authority in Buyer Organization, whereby Buyer organization is solely responsible for the impact of these clauses on the bidding process, its outcome, and consequences thereof including any eccentricity / restriction arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms and conditions governing the bid. If any clause(s) is / are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void and such bids may be cancelled by GeM at any stage of bidding process without any notice:-

- 1. Definition of Class I and Class II suppliers in the bid not in line with the extant Order / Office Memorandum issued by DPIIT in this regard.
- 2. Seeking EMD submission from bidder(s), including via Additional Terms & Conditions, in contravention to exemption provided to such sellers under GeM GTC.
- 3. Publishing Custom / BOQ bids for items for which regular GeM categories are available without any Category item bunched with it.
- 4. Creating BoQ bid for single item.
- 5. Mentioning specific Brand or Make or Model or Manufacturer or Dealer name.
- 6. Mandating submission of documents in physical form as a pre-requisite to qualify bidders.

- 7. Floating / creation of work contracts as Custom Bids in Services.
- 8. Seeking sample with bid or approval of samples during bid evaluation process. (However, in bids for <u>attached categories</u>, trials are allowed as per approved procurement policy of the buyer nodal Ministries)
- 9. Mandating foreign / international certifications even in case of existence of Indian Standards without specifying equivalent Indian Certification / standards.
- 10. Seeking experience from specific organization / department / institute only or from foreign / export experience.
- 11. Creating bid for items from irrelevant categories.
- 12. Incorporating any clause against the MSME policy and Preference to Make in India Policy.
- 13. Reference of conditions published on any external site or reference to external documents/clauses.
- 14. Asking for any Tender fee / Bid Participation fee / Auction fee in case of Bids / Forward Auction, as the case may be.

Further, if any seller has any objection/grievance against these additional clauses or otherwise on any aspect of this bid, they can raise their representation against the same by using the Representation window provided in the bid details field in Seller dashboard after logging in as a seller within 4 days of bid publication on GeM. Buyer is duty bound to reply to all such representations and would not be allowed to open bids if he fails to reply to such representations.

All GeM Sellers / Service Providers are mandated to ensure compliance with all the applicable laws / acts / rules including but not limited to all Labour Laws such as The Minimum Wages Act, 1948, The Payment of Wages Act, 1936, The Payment of Bonus Act, 1965, The Equal Remuneration Act, 1976, The Payment of Gratuity Act, 1972 etc. Any non-compliance will be treated as breach of contract and Buyer may take suitable actions as per GeM Contract.

This Bid is also governed by the General Terms and Conditions/ यह बिड सामान्य शर्तों के अंतर्गत भी शासित है

In terms of GeM GTC clause 26 regarding Restrictions on procurement from a bidder of a country which shares a land border with India, any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is registered with the Competent Authority. While participating in bid, Bidder has to undertake compliance of this and any false declaration and non-compliance of this would be a ground for immediate termination of the contract and further legal action in accordance with the laws./जेम की सामान्य शर्तों के खंड 26 के संदर्भ में भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद पर प्रतिबंध के संबंध में भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद पर प्रतिबंध के संबंध में भारत के साथ भूमि सीमा साझा करने वाले देश के लिए तभी पात्र होगा जब वह बिड देने वाला सक्षम प्राधिकारी के पास पंजीकृत हो।बिड में भाग लेते समय बिडर का इसका अनुपालन करना होगा और कोई भी गलत कामाप्त करने और कानून के अनुसार आगे की कानूनी कार्रवाई का आधार होगा।

---Thank You/धन्यवाद---