



**ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BIBINAGAR,
Hyderabad Metropolitan Region, TELANGANA - 508126**

अखिल भारतीय आयुर्विज्ञान संस्थान, बीबीनगर,
हैदराबाद मेट्रोपोलिटन क्षेत्र, तेलंगाना - 508126

File: AIIMS/BBN/ MSO/DMS/2022-23/ 1306

Date: 29 -12-2022

Subject: Proposal for Purchase of Microdebrider Debrider at AIIMS, Bibinagar- Inviting
Comments/Objection thereon.

The institute is in the process of purchasing Microdebrider Debrider on proprietary basis from M/s Medtronic Xomed, Inc., 6743 south point drive N, Jacksonville, FL 32216, USA at AIIMS, Bibinagar through its authorized distributor M/s S.K Enterprises, #6-2-9/1, Azam Towers, Flat. No- 301, 3rd Floor, Lakdi-ka Pool, Hyderabad-500004, Telangana. The proprietary certificate & Authorization Letter submitted are attached and uploaded on website.

The above documents are being uploaded for open information to submit objections/comments (if any), from any manufacture regarding proprietary nature of the above items within 21 days from the date of issue/uploading of the notification.

The comments should be sent to the Medical Superintendent, All India Institute of Medical Sciences, Bibinagar, Hyderabad Metropolitan Region (HMR), Telangana -508126 by post on or before 21 days from the date of publishing on website, failing which it will be presumed that any other vendor is having no comments to offer and case will be decided on merits.

N. Agaswal
29.12.2022

Medical Superintendent
AIIMS Bibinagar

Enclosure: Related Documents

SUB: PROPRIETARY ARTICLE CERTIFICATE

To Whom It May Concern:

Medtronic Xomed, Inc., located at 6743 South point Drive North, Jacksonville, FL 32216, USA hereby certify that the following Medtronic products below are our proprietary items, exclusively manufactured by Medtronic Xomed, Inc., in their facility at Jacksonville, USA.

Sl. No	CODE	Nomenclature
01	1898001	CONSOLE 1898001 IPC ROHS
02	1898430	FOOT SWITCH 1898430 ROHS
03	1899200	MICRODEBRIDER 1899200 M5 ROHS

No other makes or supplier is acceptable to supply the above goods for the following reasons.

1. The goods are specifically designed to work together as medical device as defined by Medtronic Inc. USA
2. All aspects of quality control and customer support for the above goods are provided by the Medtronic Inc. USA and its subsidiary office in India.

The above statement (s) are true and accurate to the best of my knowledge.

Signed on behalf of Medtronic Xomed, Inc.



Michelle Dison
Regulatory Affairs Coordinator
October 5, 2022

Medtronic

India Medtronic Pvt. Ltd.
CIN: U33110MH1993PTC204814
4th Floor, Tower A & B, SAS Tower,
The Medicity Complex,
Sector 38, Gurgaon-122001,
Haryana, India

Tel: +91 0124-470 9800

www.medtronic.co.in

October 21, 2022

Letter of Intimation of Our Authorized Distributor

To,
AIIMS Bibinagar,
Telangana.

Dear Sir/Ma'am,

This letter by India Medtronic Private Ltd located at 1261, Solitaire Corporate Park, Bldg. No. 12, 6th Floor, Andheri - Ghatkopar Link Road, Andheri (East), Mumbai - 400093, India is for the information that S.K. Enterprises, having its principal place of business at # 6-2-9/1, Azam Towers, Flat.No.301, 3rd Floor, Lakdi-Ka Pool, Hyderabad-500004, Telangana, is as on today and until 30th April, 2023 the only authorized distributor of India Medtronic Private Limited to supply Product range ENT in your institute, unless India Medtronic Pvt Ltd decides to alter/amend the same.

As there are no written terms and conditions of the sale with your esteemed organization, S.K. Enterprises, having its principal place of business at # 6-2-9/1, Azam Towers, Flat.No.301, 3rd Floor, Lakdi-Ka Pool, Hyderabad-500004, Telangana, will only be responsible for complying with the terms of sale, barring Medtronic's standard support on warranty towards equipment sold.

Yours Faithfully,
For India Medtronic Pvt Ltd



Digitally signed by R
Sanjeev Kumar Nair
Date: 2022.10.21
12:49:20 +05'30'

Authorized Signatory
Sanjeev R. Nair
Sales Lead – PM, RI & Govt Projects

Specifications of Microdebrider

Specification for Handpiece

- Should fulfil the purpose of surgeries related to Otolaryngology, Sinus Surgeries, Head & Neck Surgeries, Tonsillectomy and Skull-base procedures.
- Should be able to work up to the speed of 25000-30000 RPM in forward rotation and 5000-7500 RPM in oscillation mode.
- Should have direct-drive motor with straight through suction to reduce clogging and allow efficient tissue removal.
- Should have Gearless operation.
- Should have fingertip control to rotate the tip of blade alone up to 360 deg.
- Should have integrated blade locking system to lock the blade rotation.
- Should have integrated side grooves and cable clips to provide better tubing management.
- Should have Titanium body to avoid rusting.
- Should have the press lock to lock the blades.
- Should have a support for navigation blades & burs.
- Should have an Auto-clavable rubber hand grip for better hand control in the hand piece.
- Should be supplied with Rotatable Tricut Straight blade 11 cm long, 4mm diameter - 5 Pieces
- Should be supplied with Adenoidectomy blades, 11 cm long, 4mm diameter, 40 degree curved – 5 Pieces
- Should be supplied with Frontal Sinus blades 11 cm long, 4mm diameter, 60 degree curved – 5 Pieces

Specifications for Console:

- Apart from microdebrider attachment, it should support drill attachment for skull base work and sucker attachment for stapes surgery.
- Should have integrated irrigation system with 2 irrigation pumps.
- There be a foot control switch.
- There should be a drill attachment with short and long contra-angle hand piece.
- The speed should be above 60000 rpm.
- Should have otological micro-burr attachment.
- Should have ability to drive Endoscope lens cleaning system.
- Should be able to provide warning for handpiece error
- Should be able to change mode of motor rotation: forward or reverse or oscillation from footswitch.
- Should be easily mobile.

- Should be able to toggle between different handpieces from footswitch.
- Should comply with IEC 60601-1, EN 60601-1, IEC 60601-1-4 standard
- Type Test Report for conformity of parameters from any ILAC/NABL accredited/Central Gov. LAB should be available.

Terms and Conditions

- The bidder should produce document of supplying the implants, equipment, and instruments to at least 6 Medical Colleges/ Medical Institutes.
- The bidder should come for Demonstration and Quality Check before finalizing.
- Bidder should produce the OEM Certificate.
- Total cost of implant shall be quoted for a given serial number in the aforementioned list for the selection of L1 Vendor.
- Separate pricing quotation for components along with total price in tabulated form should be submitted for each serial numbers with individual prices for different sizes mentioned.
- All components mentioned under Indian category should be standard and ISO/GMP/FDA (Indian) certified.
- All components mentioned under Imported category should be standard and FDA/CE/ISO certified.
- Manufacturing details of all components with necessary authorizations, experience, supply details to Govt agencies, Establishments all over India shall be furnished.
- The supplier should appoint requisite personnel on site to discharge responsibility of taking requisitions for supply of product and supply the same along with necessary assistance during surgery to sort out and hand over specified items.
- The supplier shall give a declaration in writing that their company is not supplying the similar product at a lesser price to any other Government Institutions. If found so, the supplier shall abide by and supply at a price, whichever is lesser.