



अखिल भारतीय आयुर्विज्ञान संस्थान, रायपुर (छत्तीसगढ़)
All India Institute of Medical Sciences, Raipur (Chhattisgarh)
Tatibandh, GE Road,
Raipur-492 099 (CG)
www.aiimsraipur.edu.in

No: AIIMS/R/CS/VD/2024/

Date: 10.12.2024

Call for Objection

Subject: Inviting comments/objection, if any before declaring proprietary article for procurement of "Enteral Feeding Pump" for Various Department at AIIMS, Raipur.

Surgical Gastroenterology & CCU Department at AIIMS, Raipur has to procure Enteral Feeding Pump" through Proprietary Article basis.

The proposal submitted by M/s Fresenius Kabi AG, Germany who is sole manufactures and M/s ICU Surgicare, Raipur is the Local Agent of this item along with Proprietary Article Certificate are attached & uploaded on GeM Portal & Institute website.

The above documents are being uploaded for open in formation to submit objections, comments if any from any manufacturer/supplier before declaring proprietary article of the said equipment/items to be procured, within 10 days (i.e.20.12.2024) from the date of issuance/uploading of the notification.

The objection should be raised in the technical compliance sheet as enclosed, if any firm claiming suitability of their product with respect to specification mentioned.

The comments should be sent to the office of Central Store Office on above address at AIIMS Raipur in a sealed envelope with above reference on sent to respective mail address storesofficer.cp@aiimsraipur.edu.in on before 20.12.2024 up to 05:00PM from the date of uploading on institutional website, failing which it will be presumed that any other manufacture/vendor is having no comment to offer and case will be decided on merits.

Stores Officer
AIIMS Raipur (CG)
संभार अधिकारी (के क्रय)
Stores Officer (CP)
एम्स, रायपुर (छ.ग.)
AIIMS Raipur (C.G.)



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स्वामित्वप्रमाणपत्र
Proprietary Article Certificate


फाइल संख्या औरसंदर्भ File Number and Reference		
1	सामाग्रीकाविवरण Description of article	Enteral feeding pump.
2	पूर्वानुमानितमात्रा / वार्षिकआवश्यकता Forecast of quantity/ annual requirement	04 (FOUR)
3	उपरोक्तमात्रा हेतुअनुमानितमूल्य Approximate estimated value for above	[REDACTED]
4	निर्माताकानाम एवं पता Maker's name and address	Fresenius Kabi AG, Germany
5	अधिकृतडीलर / स्टॉकिस्टकानाम Name(s) of authorised dealers/stockists	M/s I do Surgicare, Raipur
6	<p>मैंपी ए सी के आधारपरउपरोक्त खरीदकोस्वीकारकरताहूँऔर यह प्रमाणित करताहूँकि: नोट- (बी), (सी-1) या (सी-2) में से केवल एक कोबनाए रखने के लिए टिककरें, जोभीलागूहोऔरदूसरोकोकाट दें। कृपया (ए) टिककरपुष्टिकरेंइसकेबिनापीएसीप्रमाणपत्र अवैध होगा</p> <p>I approve the above purchase on PAC basis and certify that:- Note- Tick to retain only one out of (b), (c-1) or (c-2) whichever is applicable and cross out others. Please do confirm (a) by ticking it - without which PAC certificate will be invalid.</p>	
6 (a)	यह एकमात्र फर्महैजोइसमदकानिर्माण / संग्रहणकररहाहै। और This is the only firm who is manufacturing /stocking this item. AND	✓
6 (b)	किसीअन्य फर्म द्वारासमरूपमदनिर्मित / विक्रय नहीं कियाजाताहै, जिसकाउपयोगइसकेबदलेकियाजासकताहै। अथवा A similar article is not manufacturing/sold by any other firm, which could be used in lieu OR	✓
6 (c-1)	कोईअन्य मेक / ब्रांडनिम्नलिखितकारणो (जैसेओईएम / वारंटी के) के लिए उपयुक्त नहीं होगा। अथवा No other make/brand will be suitable for following tangible reasons (like OEM/warranty spares): OR	

	
6 (c)	कोईअन्य मेक / ब्रांडनिम्नलिखितकारणो से उपयुक्त नहीं होगा (अगर पीएसीपिछले खरीदमेंभीदियागयाथा, तोकृपयाइसकेबाद से अधिकस्रोतोका पता लगाने के लिए प्रयास करें)तथा No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources): OR	

	प्रस्ताव के लिए वित्त शाखा की सहमतिकासंदर्भ(कार्रवाई भंडारऔरलेखाविभाग द्वारा की जायेगी) Reference of concurrence of finance wing to the proposal (Action will be taken by stores & Account Department)	_____

पिछलेतीनसालोमेंइसमद की पीएसी खरीदकाइतिहासनीचेदियाजासकताहै (यदि कोई हो)History of PAC purchase of this item for past three years may be given below (if any) None			
प्रदायककानाम Name of the Supplier			
आदेश / निविदासंदर्भऔरदिनांक Order/Tender reference & Date	आदेशितमात्रा Quantity Ordered	आदेशपरमूलदर (<input type="checkbox"/>) Basic Rate on order (<input checked="" type="checkbox"/>)	प्रतिकूलप्रदर्शनरिपोर्टअगरकोईहो Adverse Performance Reported if any

अनुमोदनकरनेवालेप्राधिकारीकाहस्ताक्षर.....


Dr. Souvik Paul
MBBS, MS, DNB SS (Surg. Gastro)
Assistant Professor
Dept. of Surgical Gastroenterology
AIIMS, Raipur (C.G.)

दिनांक 04.03.2024

अधिकारीकापदनाम Dr. Souvik Paul

General Guidelines

1. The indenting person should be In-charge/officer/faculty of the department and the Purchase Proposal Request form [PPRF] must be routed through Head of the Department (HoD).
2. **Medical Equipment** should be put up on **Assessment Committee** for approval.
3. For all procurement, specification is attached with PPRF. Specification must be by name seal & signature by the indenting person. Specification must be generalizemanner/nature which will be widely applicable to the manufactures.
4. For consumable items/medicine items, **pack size** must be mentioned by the indenting person.
5. Estimation of the rate (Purchase Order or Quotation) must be by name seal & signature by the indenting person.
6. If, item is required in Urgency details Justification should mention with emergency requirement duly signed by indenting person & must be routed through HoD.
7. Period of Rate contract (RC) should be clearly mentioned for RC procurement as per General Financial Rules (GFR).
8. On PAC procurement, Manufacture Proprietary certificate (Notarized) must be attached with PAC & also seal & signature by the indenting person & HoD.
9. As per the Manual of Procurement of Goods, **No item should be procured on PAC basis for more than three years, after which a mandatory Open Tender mode may be used, to test the market.** Therefore no item will be purchased through PAC basis.
10. Estimated/Approx. cost should be reasonable as per prevailing market rates.
11. Detail of last purchased submitted for the same item either through M/s HITES M/s HLL, GeM or other mode.
12. As per the order/Guidelines of the Govt. of India, the purchase of all equipment/items through **GeM is mandatory** & also **Make in India** is preferred.
13. It is mandatory to give details of consumption/utilization of consumables /medical consumables / medicines.
14. Same Equipment's/instruments (PPRF is being filled) kept on the department must be mentioned on **Stock Held on date.**
15. Equipment/items should be within the budget allocated by the Finance Department.
16. **Repeatedly purchased consumable items/medicines should be purchased on Rate Contract.**
17. Before filling the PPRF, review the work allocation Office order no. **22/18/2019/Admin/1319** Dt. 30/09/2019, Manual of Procurement of Goods & General Financial Rules (GFR).

Technical specifications of Feeding pump

A. Feeding:

1. **Flow rate range & feeding volume:**
 - i. **Continuous mode:**
 - a. Volume: 1 – 5000 mL (1 mL increments)
 - b. Flow rate: 1 – 600 mL/h (1 mL/h increments)
 - ii. **Bolus mode:**
 - a. Bolus Volume: 1-5000 mL (1 mL increments)
 - b. Flow rate: 1-600 mL/h (1 mL/h increments)
 - c. Bolus Number: 1 - 24, unlimited
 - d. Intervals: 15 min - 24 h (15 min increments)
 - iii. **Delivery Progress and Remaining Time displayed** with VTBI (volume to be infused) selection (if Target Volume available)
2. **Flow rate accuracy:** +/- 5 % at 50 mL/h
3. Feeding mode: Continuous and bolus
4. **Priming:** Automatic, semi-automatic and manual priming should be available
5. **Counter:** Cumulative feeding volume counter from 0.001 L to 99.999 L
6. **Data event log:**
 - i. Feeding history: 200 events
 - ii. Alarm history: 150 events
7. **Night mode:** The night mode must be available to decrease the brightness of the screen and the power LED
8. **Keypad lock:** must be available for disabling keypad to prevent unintentional key press
9. **Setting lock:** must be available for possibility to prevent patient from changing settings, access code protected
10. **Other settings:**
 - i. Target volume activation/deactivation
 - ii. Flushing information activation/deactivation
 - iii. Sound level adjustment
 - iv. key beep activation/deactivation
 - v. contrast & brightness settings
 - vi. time between alarm sounds setting
 - vii. time between the target volume almost reached the message and the target volume reached the setting.
 - viii. Should have flushing indicator to remind user to flush in between bolus
 - ix. Should have reset function to enable user to reset all the parameters to factory default
11. **Intended use:** For enteral feeding use only

B. Information / Alarms:

1. **Pump status:**
 - i. Administration in progress: Droplet animation

- ii. Administration stopped: Stop symbol displayed
- iii. Administration on hold (during Bolus Interval Time): Droplet animation

2. **Information:**

- i. Start reminder, flushing information, technical information available via the menu.

3. **Alarms:**

- i. Target volume almost reached, battery almost discharged, target volume reached, door opened, wrong set installation, downstream occlusion, upstream occlusion, empty bag / air in line, empty battery, technical error. All alarms represented by light indicators, pictograms and sounds.

4. **Occlusion detection time:** At 50 mL/h: < 6 min

5. **Empty bag / air in line detection time:** At 50 mL/h: < 5 min

C. Technical Details:

1. **Pumping mechanism:** Linear peristaltic pumping system

2. **Communication via Smart Holder COM: preferably be available:**

- i. Serial communication protocol for interface with Electronic Medical Record (EMR)
- ii. Nurse call system
- iii. Connection with computer for maintenance activities

3. **Display:** Monochrome LCD 41 x 60 mm (160 x 240 pixels)

4. **Clamp:** Versatile clamp to fix on a rail (10 - 35 mm) or a pole (Ø 8 - 40 mm)

5. **Dimensions (H/W/D) / Weight**

- i. Pump: Approximately 138 x 128 x 48 mm / 610 g
- ii. Pump Holder COM: Approximately 132 x 118 x 46 mm (without clamp) / 420 g

6. **Battery**

- i. 4.8 V ; 2.2 Ah NiMH (Nickel-Metal Hydride)
- ii. Battery life when fully charged: minimum 24 h at 125 mL/h (in standard feeding conditions, 22.5°C +/- 2.5°C)
- iii. Battery level indication on the display
- iv. Battery charging time: maximum 6 h
- v. Should provide 1 year warranty of battery

7. **Compliance standard: (certificates to be attached)**

- i. EN/IEC 60 601-1, EN/IEC 60 601-1-2, EN/IEC 60 601-2-24, EN/IEC 60 601-1-8 and EN/IEC 60 601-1-11
- ii. Complies with the 93/42/EEC Medical Device Directive or the Medical Device Regulation (EU) 2017/745

iii. **Waterproofness**

- a. Pump: IP35
- b. Smart Holder COM: IP32

iv. **Electrical compliance**

- a. Protection against leakage current: Defibrillation-proof type CF

- b. Protection against electric shocks: class II
8. **Power supply:** 100-240 Vac +/- 10% / 50/60 Hz +/- 1Hz
9. **Power consumption:** Maximum 9 W in standard operating conditions
10. **Noise:** Around 26 dBA at 1 m (background noise 18.3 dBA)
11. **Housing material:** ABS
- D. **Accessories:** following accessory to be supplied with the each equipment
1. Compatible Feeding bag with Gravity Sets with needed accessories - 2 quantity each
 - i. Feeding bag should have volume capacity of 1500 ml & should come with pre attached giving sets which is made up of DEHP-free & Latex-Free having length of approx 250 cms
 - ii. The Gravity set should have:
 - a. Leur Free, Latex free, DEHP free
 - b. Drip chamber and roller clamp to control enteral nutrition application
 - c. Three-way stopcock as access port
 - d. universal detachable adapter to ensure connectivity with all enteral feeding disposables
 2. Power cord minimum 2.5 meter length - 1 in number
 3. Adapter - 1
 4. Should be supplied with Swinglock clamp for versatile clamp and horizontal clamp that allows the fixation on a rail or on a pole
 5. User Manual
- E. The equipment should have an MD license from CDSCO as per the new Medical Devices regulations and It should have ISO 13485:2016 which should be either from NABCB accredited Certifying bodies or from a member body of IAF (International Accreditation Forum). (certificates to be attached)
- F. It must be BIS/ Eur CE with 4 digit notified body number / USFDA certified (certificate to be attached)
- G. Warranty and CMC: Firm shall provide 5 Year warranty and 5 years CMC.
- H. Full brochure, catalog and user manual must be attached in the technical documents.
- I. Physical Demonstration is a part of technical evaluation, if required. The technically Qualified Bidder is required to arrange a demonstration of the quoted product, if required. Failure to arrange for a demonstration on the given date may lead to cancellation of the bid. The cost of organizing such a demonstration shall be borne by the bidder.
- J. The firm should provide the details of after sales and service and application backup.
- K. Demonstration and onsite training of staff by the application experts is mandatory.
- L. The firm must have an application specialist and service engineer in the respective state.



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Fresenius Kabi AG

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61352 Bad Homburg
Germany
T- +49 6172686-0
www.fresenius-kabi.de

PROPRIETARY ARTICLE CERTIFICATE (PAC)

TO WHOMSOEVER IT MAY CONCERN

FRESENIUS KABI INDIA PRIVATE LIMITED, with registered office at A-3, MIDC, Ranjangaon Ganpati, Taluka Shirur, District Pune 412220 Maharashtra India is wholly owned subsidiary of **FRESENIUS KABI AG, GERMANY**.

FRESENIUS KABI INDIA PRIVATE LIMITED has exclusive rights to import and market Fresenius Kabi, Germany's products in India.

We hereby certify that **AMIKA (INTERNAL FEEDING PUMP)** is the proprietary product of the Fresenius Kabi Group owned by its holding company Fresenius Kabi AG, Germany.

AMIKA (ENTERLA FEEDING PUMP) is used for continuous feeding of enteral feeds to critically ill patients:

We further declare and certify that **AMIKA (ENTERLA FEEDING PUMP)** works with the following disposables only, which are too the proprietary products of Fresenius Kabi Group owned by its holding company Fresenius Kabi AG, Germany:

1. Amika Pump Set Bag
2. Freka Transnasal Feeding Tube - 15ch/100cm
3. Freka Transnasal Feeding Tube - 12CH/120cm

For Fresenius Kabi AG

KAUSHAL GUPTA
Authorized Signatory



Date: 09.08.2022



**Fresenius Kabi
India Pvt. Limited**
Fifth Floor, A- Wing, Ashoka Plaza,
Pune-Nagar Rd., Survey No. 32/2,
Vadgaon Sheri, Viman Nagar,
Pune – 411 014, India.

Ref. No.: FKIP/L/AUTH/2022/065

Dated : 01st MAR 2024

Tel. : +91 20 26634701-7

Fax. : +91 20 26624710.

Website : www.fresenius-kabi.com

To,
CENTRAL STORES
AIIMS RAIPUR
CG

AUTHORIZATION LETTER

We M/s Fresenius Kabi India Pvt. Ltd. Authorized Marketers/Importer and Subsidiary of Fresenius Kabi AG, Germany who are established and reputable manufactures of Syringe & Infusion Pumps having factories at France and China, hereby certify that **M/s. ICU SURGICARE INDIA PVT LTD, having office at Ground Floor, Building No.1, Mithi Muskan, Ring Road, near D Mart, DD Nagar, Raipur, CG-492014** are our Authorized Distributor for all our Products to be Sold/Marketed on (GeM) Government E-Marketplace.

Products/Models:

1. **AGILIA RANGE** : AGILIA SP, AGILIA SP MC, AGILIA SP PCA, AGILIA SP TIVA
2. **INFUSIA RANGE** : INFUSIA SP7, INFUSIA SP7-S, INFUSIA VP7, INFUSIA VP7S
3. **AMIKA RANGE:** AMIKA FEEDING PUMP

Validity Details

Valid From : 15th Feb 2024

Valid Till : 31st Dec 2024

This is also certified that **M/s. ICU SURGICARE INDIA PVT LTD** are authorized to Quote their Own Rates, take supply orders and raise invoice thereof.

Validity of the said authorization may be extended further on mutual consent.



Yours Faithfully,
Durgesh Gupta
Divisional Manager
Fresenius Kabi India Pvt. Ltd.