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भारत सरकार/Government of India
स्वास्थ्य और परिवार कल्याण मंत्रालय/ Ministry of Health and Family Welfare
प्रधानमंत्री स्वास्थ्य सुरक्षा योजना/PMSSY
अखिल भारतीय आयुर्विज्ञान संस्थान/All India Institute of Medical Sciences
मंगलगिरि, आंध्र प्रदेश/Mangalagiri, Andhra Pradesh

No.: AIIMS MG/Procurement/ PAC /2021-22/ Minimally Invasive Cardiac output monitor

Date: 11/05/2022

CALL FOR OBJECTION

AIIMS Mangalagiri has a requirement of **Minimally Invasive Cardiac Output Monitor** for the department of Anaesthesia. In this regard comments/ objection, if any are invited before declaring the article as proprietary in nature.

In this regard, the proposal submitted by **M/s Medical Bionic Pvt Ltd D.no 1-2-412/5C Gaganmahal road, Near AV College, Hyderabad** (authorised distributor of the **M/s. Edwards Life Sciences (India) Pvt ltd** of this product) along with Proprietary Article Certificate are attached and duly uploaded on Institute website for open information to submit objections/comments, if any from any manufacturer/ supplier before declaring the article of the said equipment/items to be procured as proprietary.

The objections/comments should be sent to the Faculty I/C, Procurement, 4th floor, Nursing College building, AIIMS Mangalagiri, Guntur, Andhra Pradesh 522503 in a sealed envelope with the above reference on or before 21/05/2022, 3:00 PM i.e., 10 days from today, failing which it will be presumed that any other manufacture/vendor is having no objections/comments to offer and the case will be decided on merits.


11-5-22

Asst. FIC Procurement
For Director, AIIMS Mangalagiri

Enclosure:

1. PAC of Department
2. PAC of Manufacturer
3. Manufacturer Authorization form

Email: Procurement@aiimsmangalagiri.edu.in

P-3 FORM

(to be attached with P-2 form for Proprietary items)

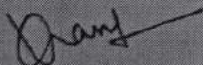
AIIMS Mangalagiri

PROPRIETARY ARTICLE CERTIFICATE

It is certified that the items Minimally Invasive Cardiac Output Monitor (Make: Edwards Lifesciences, Model: Hemosphere Advanced Monitor) required in the P-2 form should be purchased from M/s. Edwards Lifesciences. To the best of my knowledge M/s Edwards Lifesciences are the sole manufacturer/ agents of the sole manufacturers

Similar items manufactured by other firm(s) shall not be suitable for our purpose for the following reasons:

1. Delivers advance pressure and flow parameters for managing perfusion.
2. Connects to an existing radial arterial line.
3. Acumen hypotension prediction index software predicts likelihood of a hypotensive event and provides insight to understand the root cause and proactively inform a potential course of action.
4. Can measure CO/CI, SV/SVI, SVV, PPV, SVR/SVRI.


(Sign of Indenter)

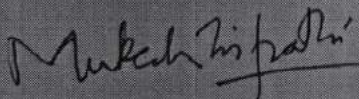
Date: 28-06-2021

DR. VAMSIDHAR CHINNELLA
KMC Regd. No : 81249
Asst. Professor
Dept. of Anesthesiology
AIIMS MANGALAGIRI

Designation: Assistant Professor

Department: Anesthesiology

Recommend at on:


Signature of Head of Department/Section
HOD, Department of Anesthesiology

N.B. All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh
Before recording the above certificate should satisfy himself that the article is genuine and proprietary nature manufactured under patent laws.



Edwards

Proprietary Article Certificate

January 29, 2021

To Whom it may concern

We hereby certify that M/s. Edwards Lifesciences LLC located at One Edwards Way, Irvine, CA 92614 USA, is the sole legal manufacturer of the HemoSphere advanced monitoring Platform.

Product Description/ Intended Use

The HemoSphere advanced monitor is intended to be used in combination with a compatible Edwards hemodynamic monitoring technology module and/or cable and accompanying Edwards accessories and/or disposables.

The HemoSphere advanced monitor when used with the HemoSphere Swan-Ganz module and Edwards Swan-Ganz catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of cardiac output (continuous [CO] and intermittent [iCO]) and derived hemodynamic parameters in a hospital environment.

The HemoSphere advanced monitor when used with the HemoSphere oximetry cable and Edwards oximetry catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of venous oxygen saturation (SvO2 and ScvO2) and derived hemodynamic parameters in a hospital Environment.

The HemoSphere advanced monitor when used with the HemoSphere pressure cable is indicated for use in critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment.

The HemoSphere tissue oximetry module is intended for use with the HemoSphere advanced monitor and the FORE-SIGHT ELITE tissue oximeter module (FSE module) to measure tissue oxygen saturation, StO2.

The noninvasive FORE-SIGHT ELITE tissue oximeter module is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the Sensors in individuals at risk for reduced-flow or no-flow ischemic states. The FORE-SIGHT ELITE tissue oximeter module is intended to allow for the display of StO2 on the HemoSphere advanced monitor.

- When used with large sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for use on adults and transitional adolescents ≥ 40 kg.
- When used with Medium Sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for use on pediatric subjects ≥ 3 kg.

Edwards Lifesciences LLC
One Edwards Way, Irvine, CA USA 92614
Phone: 949.250.2500 Fax: 949.250.2525 www.edwards.com



- When used with Small Sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5kg.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

The HemoSphere is covered by the following US Patent relating to our Proprietary HemoSphere Swan Ganz Modules

Patents	US issue Date	US Expiry Date
United States Patent 7,220,230	05-22-2007	02-23-2025
United States Patent 7,452,333	11-18-2008	04-19-2025
United States Patent 7,422,562	09-09-2008	05-21-2025
United States Patent 7,785,263	08-31-2010	03-31-2024
United States Patent 7,967,757	06-28-2011	06-08-2024
United States Patent 8,721,556	05-13-2014	12-05-2023

Sincerely,

Min Park

Digitally signed by
Min Park
Date: 2021.01.29
09:29:18 -08'00'

Min Jeong Park
Sr. Regulatory Affairs Specialist Edwards
Lifesciences LLC

Edwards Lifesciences LLC
One Edwards Way · Irvine, CA USA · 92614
Phone: 949.250.2500 Fax: 949.250.2525 · www.edwards.com



Edwards

February 4, 2022

To,
All India Institute Of Medical Sciences (aiims)
Vijayawada Andhra Pradesh

Dear Sir,

Sub: Letter of Authority to M/S Medical Bionic Pvt Ltd for making quoting & supplies

Ref: GEM/2022/B/1856535 Dated: 28-01-2022 Minimally Invasive Cardiac Output Monitor (Edwards Lifesciences, Hemisphere Advanced Monitor)

Dear Sir,

This is with reference to the captioned subject. Please note that M/S Medical Bionic Pvt Ltd, Having Office At 1-2-412/15C Gaganmahal Road, Near AV College, Hyderabad - 29. Ph: 66416288 ,66410999 Or 66416290 are the authorized distributor of Edwards Lifesciences (India) Private Limited (hereinafter referred to as "Edwards") having its Registered Office at 4th Floor, Commerz II, International Business Park, Oberoi Garden City, Off. Western Express Highway, Goregaon (East), Mumbai 400 063'.

M/S Medical Bionic Pvt Ltd are duly authorised to quote , receive orders, make supplies and collect payment etc. for Edwards Critical Care range of products and Edwards Vascular range of products on our behalf to your esteemed Institute.

Further, please note that no other distributor is authorised to quote for the tender or make supplies to your Institute on our behalf other than M/S Medical Bionic Pvt Ltd.

This authorisation letter shall be valid until December 31, 2022, WITH A PROVISION TO EXTEND THE SAME FURTHER..

Please take note of the same.

Yours faithfully,

For Edwards Lifesciences (India) Private Limited

Wee
Yao
Ng
Wee Yao NG
Managing Director

Digitally signed by
Wee Yao NG
DN: cn=Wee Yao
Ng,
email=Wee_Yao_
ng@edwards.com,
Date: 2022.02.04
17:15:00 +05'30'

Cc: M/S Medical Bionic Pvt Ltd

Edwards Lifesciences (India) Private Limited

Regd. Office: 4th Floor, Commerz II, International Business Park, Oberoi Garden City,
Off. Western Express Highway, Goregaon (East), Mumbai 400063

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