



CALL FOR OBJECTION NOTICE

Subject:- Purchase of consumables for Advanced Flotrac Cardiac Output Monitor, Model:HemoSphere and manufactured by Edwards LifeSciences, and supplied by M/S Fama Marketing for use in the Deptt. of Anaesthesiology, RIMS, Imphal – inviting comments/objections thereon

This Institute is in the process for purchasing of consumables for Advanced Flotrac Cardiac Output Monitor Model: HemoSphere and manufactured by Edwards LifeSciences for use in the Deptt. of Anaesthesiology, RIMS, Imphal, on Proprietary nature from M/S Fama Marketing, Guwahati, the authorized distributor of Edwards LifeSciences. The proposal submitted by M/S Fama Marketing, Guwahati and Proprietary Article Certificate (PAC) with relevant documents are enclosed.

2. The above documents are being uploaded at RIMS website for an open invitations to all stakeholders to submit obligation/ objections, from the relevant manufacturers across India, regarding the proprietary and cost of nature of the consumables, within 10 days from the date of issue of this Notice, with reference to GEM Contract No. GEMC-511687728381516 dated 11th Feb, 2025 for purchase of Advanced Flotrac Cardiac Output Monitor Model: HemoSphere supplied by M/S Fama Marketing, Guwahati and manufactured by Edwards LifeSciences.

3. The comments should reach RIMS, Imphal, at official E-mail: rims.imphal@gov.in on or before 1st Aug., 2025 upto 4:00 P.M., failing which, it will be presumed that stakeholders have no objection to the Proprietary Nature of the consumables mentioned below:-

Sl. No.	Consumables Items
1	AIQS85 (Arterial Transducer)
2	AIQCM (Finger Cuff)
3	PX600F (CVP transducer)
4	TCLIP05 (Transducer Holder)
5	EVHRS (Heart Reference Sensor)
6	FSESL (Foresight Sensor Large Size)

Encl: As stated above.

Signed by

Mecolt Rajkumar Singh

Date: 18-07-2025 13:27:17

(R.K. Mecolt Singh)

Deputy Director(Admn.)

Copy to:-

1. P.S. to the Director, RIMS, Imphal – for kind information
2. The HOD, Anaesthesiology, RIMS, Imphal
3. The CAO/FA, RIMS, Imphal
4. The System Administrator, RIMS, Imphal- for uploading the "Call for Objection" Notice with other relevant documents to RIMS website.
5. Guard File

PROPRIETARY ARTICLE CERTIFICATE

(Procurement of the Goods under the provision of Rule 166 of GFR 2017- Procurement base on Single Tender Enquiry)

The indenter hereby certify that

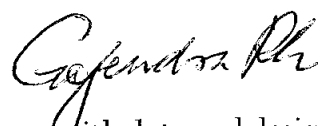
1. The indented goods/software are manufactured/developed by
M/s Edwards LifeSciences

Sl. no.	Consumables	Qty. (1 year requirement Approx.)
i	AIQS85 (Arterial transducer)	20 boxes
ii	AIQCM (Finger cuff)	100 boxes
iii	PX600F (CVP transducer)	5 boxes
iv	TCLIP05 (transducer holder)	2 boxes
v	EVHRS (Heart reference sensor)	2 units
vi	FSESL (Foresight sensor large size)	2 boxes

2. No other make or model /software is acceptable for the following reasons:

PAC submitted physically.

3. Supporting documents from supplier attached: Yes



Signature with date and designation
of the indenting officer
Professor & Head
Deptt. of Anaesthesiology
RIMS, Imphal



Signature with date,
HOD, Anaesthesiology, RIMS, Imphal

Professor & Head
Deptt. of Anaesthesiology
RIMS, Imphal



Edwards

Proprietary Article Certificate

April 28, 2025

To Whom It May Concern

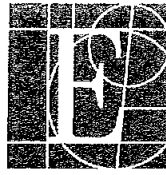
We hereby certify that **Edwards Lifesciences LLC** located at **One Edwards Way, Irvine, CA 92614 USA** is the sole legal manufacturer of the products below:

Device Name	Intended Use	Model Code
Acumen IQ Sensor	Acumen IQ sensor is indicated for use in intravascular pressure monitoring. It is also indicated for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output.	AIQS8, AIQS85
Acumen IQ Finger Cuff	The Acumen IQ and ClearSight finger cuffs are indicated for patients over 18 years of age to noninvasively measure blood pressure and associated hemodynamic parameters when used with EV1000 clinical platform NI or HemoSphere advanced monitoring platform.	AIQCS, AIQCM, AIQCL

Sincerely,

Ramin Aminian
Digitally signed by
Ramin Aminian
Date: 2025.04.28
12:49:15 -07'00'

Ramin Aminian
Sr. Specialist, Regulatory Affairs
Edwards Lifesciences LLC



Edwards

Proprietary Article Certificate

October 6, 2020

To Whom it may concern

We hereby Certify that Edwards Lifesciences LLC located at One Edwards Way, Irvine, CA 92614 USA is the sole legal manufacturer of the following pressure monitoring kits:

Device Name	Intended Use	Model code
TruWave Pressure Monitoring Set	The Pressure Monitoring Kit with TruWave Disposable Pressure Transducer is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.	PX600F

Sincerely,

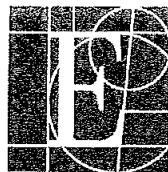
Min Park

Digitally signed by
Min Park
Date: 2020.10.06
09:18:34 -07'00'

October 6, 2020

Date

Min Jeong Park
Sr. Regulatory Specialist
Edwards Lifesciences LLC



Edwards

Proprietary Article Certificate

June 4, 2020

To Whom it may concern

We hereby Certify that Edwards Lifesciences LLC located at One Edwards Way, Irvine, CA 92614 USA is the sole legal manufacturer of the below mentioned product in table:

Product Description	Intended Use	Model code
Pressure Monitoring Accessory	TRUCLIP is intended to be mounted to an IV pole or bed railing to hold Edwards Lifesciences pressure monitoring, arterial pressure cardiac output (APCO) and blood sampling devices.	TRUCLIP

TCL1P05

Sincerely,

**Min-Jeong
Park**

Digitally signed by
Min-Jeong Park
Date: 2020.06.04
09:55:46 -07'00'

Min-Jeong Park
Sr. Regulatory Affairs specialist
Edwards Lifesciences LLC

June 4, 2020



Edwards

Proprietary Article Certificate

April 28, 2025

To Whom It May Concern

We hereby certify that **Edwards Lifesciences LLC** located at **One Edwards Way, Irvine, CA 92614 USA** is the sole legal manufacturer of the products below:

Device Name	Intended Use	Model Code
Heart Reference Sensor	The heart reference sensor is intended for use with a compatible Edwards noninvasive monitoring system - composed of compatible monitor, pressure source (pump), heart reference sensor, compatible Edwards finger cuff(s) and pressure controller - for noninvasive measurement of blood pressure and associated hemodynamic parameters. Refer to the operator's manual of the compatible Edwards monitor being used for specific information on the intended use environment and patient population. Device performance, including functional characteristics, have been verified in a comprehensive series of testing to support the safety and performance of the device for its intended use when used in accordance with the established Instructions For Use.	EVHRS
Pressure Controller Kit	The pressure controller is intended for use with an Edwards compatible noninvasive monitoring system - composed of compatible monitor, pressure source (pump), heart reference sensor, compatible Edwards finger cuff(s) and pressure controller - for noninvasive measurement of blood pressure and associated hemodynamic parameters. Refer to the operator's manual of the compatible Edwards monitor being used for specific information on the intended use environment and patient population.	PC2K, HEMPC2K

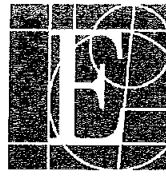
Sincerely,

Ramin Aminian
Digitally signed
by Ramin Aminian
Date: 2025.04.28
12:53:23 -07'00'

Ramin Aminian

Sr. Specialist, Regulatory Affairs

Edwards Lifesciences LLC



Edwards

Proprietary Article Certificate

December 9, 2021

To Whom it may concern

We hereby Certify that Edwards Lifesciences LLC located at One Edwards Way, Irvine, CA 92614 USA is the sole legal manufacturer of the following devices.:

Device Name	Intended Use	Model code
Fore-Sight Elite Sensor, Large	The large Sensor is indicated for monitoring of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced flow or no-flow ischemic states. It is intended for use on adults and transitional adolescents ≥ 40 kg.	FSESL
Fore-Sight Elite Sensor, Medium	The medium Sensor is indicated for monitoring of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced flow or no-flow ischemic states. It is intended for use on pediatric subjects ≥ 3 kg.	FSESM
Fore-Sight Elite Sensor, Small	The small Sensor is indicated for monitoring of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced flow or no-flow ischemic states. It is intended for cerebral use on pediatric subjects < 8 kg and non-cerebral use on pediatric subjects < 5 kg.	FSESS
Fore-Sight Elite Sensor, Neonatal Small	The small Sensor is indicated for monitoring of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced flow or no-flow ischemic states. It is intended for cerebral use on pediatric subjects < 8 kg and non-cerebral use on pediatric subjects < 5 kg.	FSESNS

The above information is true and accurate to the best of my knowledge.

Sincerely,

Digitally signed by Min
Park
Min Park
Date: 2021.12.09 13:35:55
-08'00'

Min Park
Sr. Regulatory Affairs Specialist, Critical Care
Edwards Lifesciences LLC

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