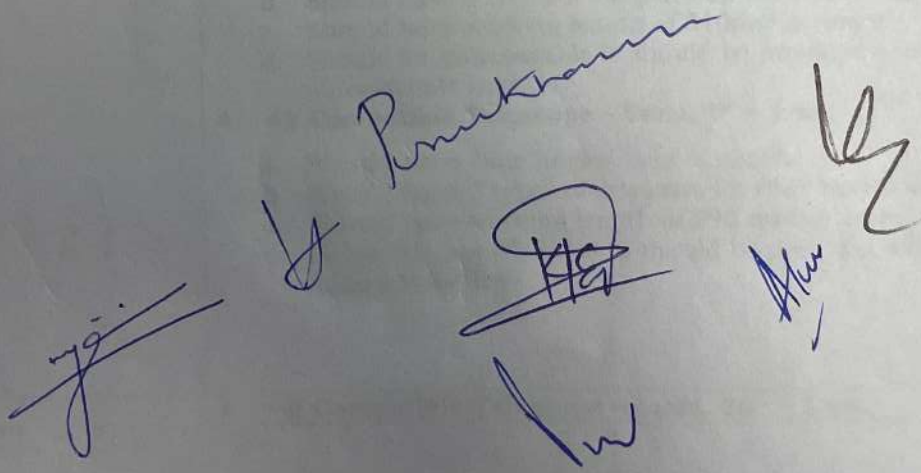


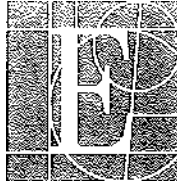
**ALL INDIA INSTITUTE OF MEDICAL SCIENCE
NEW DELHI-110029
SURGERY BLOCK**

PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE

1.	Item/Type Model Number required along with specification.	Flow Track Cardiac Output Monitor
2.	It the item a spare part attachment or accessory for an existing equipment.	No
3.	Name of the manufactures/supplier of the item proposed by the indenter.	M/s. Edwards Lifesciences (India) Pvt. Ltd. Supply through: M/s. Speciality Pharma (Authorized Indian agent).
4.	Are the sole manufactures/sole distributors of the item?	Yes
5.	It there any other item with similar/equipment specifications available in the market to meet the job requirement envisaged. If the answer is yes, why the same can't procured.	No. It is specific equipment/technology which does not available with any other manufacturer/supplier.
6.	What were the efforts made to locate alternative source of supply or use other substitutes.	Internet search, enquiry from other firms/supplier available in the market of respective field.
7.	Why open/limited tender can't be resorted to, for locating alter native source.	This is specific requirement for better patient care services. As required product is not available with any other manufacturer/supplier, the open/limited tender may not be fruitful and waste of time only.
8.	Are the proprietary items certifying that the rates are reasonable or not.	Being PAC item, effort may be made to find reasonability of rates & may be negotiated by SPC/Negotiation committee.
9.	Any other justification for procuring item for single source.	To ensure better patient care service.

I certified that the item at Nr. No.1 above is required to be procured on PAC basis as the source of supply is definitely known which is meeting with functional requirement of department and limited tender system could be dispensed with as they would serve no useful purpose in the particular case.





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,

Min Park

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

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