ALL INDIA INSTITUTE OF MEDICAL SCIENCE ANSARI NAGAR NEW DELHI -110029 HOSPIRAL STORE

Dated: 08.09.2022

Reference Tender No. 38/H/Spectra Optia/2022-23/Prop.

Sub: Purchase of "Spectra Optia Platelet Phoresis Kit with ACD Bag (Product Code:10400) & Spectra Optia Exchange Kit (Product Code: 10220) & Spectra Optia Collection/IDL Kit with I ACD Bag (Product Code: 10310)" at AHMS New Delhi – 110029, on proprietary Basis inviting comments thereon.

经存货的现在分词

The institute is in the process Purchase "Spectra Optima Platelet Pheresis Kit with ACD Bag (Product Code:10400), Spectra Optima Exchange Kit (Product Code: 10220) & Spectra Optima Collection /IDL Kit with I ACD Bag (Product Code: 10310)" on One year Rate Contracts basis as Office Memorandum No. CPU/2022-23/5 at AUMS New Delhi from OEM-TERUMOBET through M/s AVN Healthcare. The PAC Certification by M/s TERUMOBET as well as the User Department are attached.

The Items Description, Product Code with HSN Code as under:

S. <u>No.</u>	Product	HSN Code
1.	Spectra Optia Platelet Pheresis Kit with ACD Bag (Product Code: 10400)	90189099
2.	Spectra Optia Exchange Kit (Product code: 10220)	90189099
3.	Spectra Optia Collection/IDL Kit with 1 ACD Bag (Product Code: 10310)	90189099

The PAC as well as the User Department documents are being upload for open information to submit objection, Comments, if any, from any manufacturer regarding proprietary nature of the Spectra Optia Platelet Pheresis Kit with ACD Bag (Product Code: 10400) & Spectra Optia Exchange Kit (Product Code: 10220) & Spectra Optia Collection/IDL Kit with 1 ACD Bag (Product Code: 10310)" within 21 days from the date of issue / uploading of the notification giving reference tender no. 38/H/Spectra Optia/2022-23/Prop. the Comments should be received in office of Stores Officer (II) At AIIMS on dated: 08/09/2022 up to 29/09/2022 time 12:30 PM. Failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

ASSTT. STORE OFFICER (II)

STOŘE ÓFFICE (II).

Encl: Related document enclosed:

SPECIFICATION

Spectra Optia Single Donor Platelet/Plasma Kit (10400)

- Extracorporeal Volume : Approximately 196 ml
- 2. The disposable should be CE marked and approved by the local authorities, with supporting documents.
- 3. Sterilization: The blood and fluid pathways of the tubing set are sterilized with ethylene oxide and are non phyllogenic. Tubing sets manufactured by Terumo BCT bearing the not for reuse symbol are intended for single use only and are not intended to be reprocessed or reused.
- 4. Expiry Date: 2 years from the date of manufacture, refer to product labelling for expiry date.
- 5. Tubing set storage condition: The product must be kept away from sunlight and must be kept in dry condition.
- 6. Inlet needle size: Gauge: 17, Cannula length: 24,3 mm
- Tubing set composition:
 - Primary tubing material: PVC plasticized with DEHP
 - Platelet storage bags: PVC plasticized with butyrltrihexyl citrate (BTHC)
 - Plasma storage bag: PVC plasticized with DEHP
 - Cassette: Polyethylene terephthalate (PET-G)
 - Sampling needle: stainless steel
 - Access needle: stainless steel
- Capacity of set bags:
 - Storage Bag specifications for platelets in Plasma. Storage parameters storage ranges condition - Platelei storage bag volume 100 to 400 ml platelet storage temperature : $22^{\circ}\text{C} \pm 2^{\circ}\text{ C}$
 - Plasma Storage bag specifications: 600 ml if product is to be frozen; 1000 ml if product is not to be frozen
- 9. Disposable usages trends can be measured using Spectra Optia equipment

Spectra Optia Peripheral Blood Stem Cell Collection Kit (IDL set 10310)

- 1. Extracorporeal volume: 249 ml under normal conditions and 297 ml maximum with a full reservoir
- 2. The disposable should be CE marked and approved by the local authorities, with supporting documents.
- 3. Sterilization: The blood and fluid pathways of the tubing set are sterilized with ethylene oxide and non pyrogenic. Tubing set manufactured by Terumo BCT bearing the not for reuse symbol are intended for single use only and are not intended to be reprocessed or reused

4. Single set, multiple protocols performs PMN collections on the same tubing set used for WBC ad platelet depletions



- 5. Expiry Date: 2 years from the date of manufacture, refer to product labelling for expiry date
- 6. Tubing set storage condition: The product must be kep away from sunlight and must be kept in dry condition
- Capacity of collection bags capacity of the storage bag 940 ml for stem cell or granulocyte collection, additional spike port available in case additional volume depletion for depletion procedures.

Spectra Optia Therapcutic Plasma Exchange Kit (TPE Set 10220)

- 1. Extracorporeal volume: 142 ml under normal conditions and 185 ml maximum with a full reservoir
- 2. The disposable should be CE marked and approved by the local authorities with supporting documents
- 3. Sterilization: The blood and fluid pathways of the tubing set are sterilized with ethylene oxide and non-pyrogenic,. Tubing set manufactured by Terumo BCT bearing the not for reuse symbol are intended for single use only and are not intended to be reprocessed or reused.
- 4. Single set, multiple protocols: Performs therapeutic plasma exchange on the same tubing set used for RBC exchange and secondary plasma device.
- 5. Expiry Date: 2 years from the date of manufacture, refer to product labelling for expiry date
- 6. Tubing set storage condition: The product must be kep away from sunlight and must be kept in dry condition

7. Capacity of waste bags: Capacity of the removal bag 6000 ml additional spike port available in case of large volume exchange.

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हाँ, हेर पेंद्र भा**ग्डेप/Dr.** Hera Charde सह राज्य**ां/Associate** Pro िंट्र ग्र**ायल औपथि वि**भाग Dr. ont of Transfusion Me.

ग्रज्यसं, ४८ करके**-29/A.H.M.S. New** Dulle 29

डॉ. पूनम कौरिक/Dr. POONAM COSHIC मुख्य चिकित्सा अधिकारी प्रभारी Chief Medical Officer In-charge एकं केंद्र भूख असवत/Since Centre Main Hospital अभाग्रहर्स, वह दिल्ही/A.H.M.S., New Dalhi-20 Dept. of Transfusion Medicing
AliMS New Delhi

Deptt. of Transfusion Medicine AIIMS, Ansari Nagar New Delbi-110029

PROPRIETORY ARTICLE CERTIFICATE (PAC)

(for chemicals, spare parts, reagents, consumables etc.)

(i)	The indented goods are manufactured by	MIS TERUM.	O PEMPOL	PNF 470
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(ii) Item Name: Option Platelet But with our AeD Bay

(iii) Model/Part/Catalogue No. 12400, 10310, 10120

(iv) Reasons/Justification which makes the requirement proprietary##

It is a cloud septem equipment where "

Consummables kits of same equipment on

Can be used:

- it is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent specifications which can fulfill the vital requirements of end user.
- It is certified that the purchase is proposed to be made on proprietary usage basis
 because any other material /equipment /instrument chemical etc. if used will lead
 to deviation and affect the integrity/accuracy, validity or analysis of the
 assignment/patient care.

Signature of TSEC

With name, Designation, Department, and Hospital/Institute/DGHS

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DEPARTMENT OF BLOOD CENTRE MAIN HOSPITAL

ALL INDIA INSTITUTE OF MEDICAL SCIENCES

ileÑo	Date: 22-06-2022
IIG/NU	

'CERTIFICATE FOR REASONABILITY OF PRICE'

It is certified that the goods/equipment i.e. Optia Platelet Plusma let week one Acd Bag 10400, 10310, 10220

(Item Name) to be purchased are of the requisite quality, quantity and specifications and has to be purchased after following due purchase procedure of the Institute. The purchase price against above mentioned tender/PAC is reasonable and recommended for purchase for the Department of Blood Cenhic Main Haspital Dept of Transfusion Medicine

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August 28, 2019

PROPRIETARY CERTIFICATE

TO WHOM IT MAY CONCERN

This is to certify that the consumables and disposables for the Trima Accel® Automated Blood Collection System and the Spectra Optia Apheresis System are manufactured by Terumo BCT and are specific to the equipment and are proprietary in nature.

The items include the following disposables:

	Trima Accel® Automated Blood Collection System
	Truna Accers Autorisates Baost Conscension
f	Platelet, Plasma Set
2	Piatelet, Piasma, RBC Set
3	RBC, Plasma Set
4	Platelet + Sampler + Auto PAS, MultiPlasma Set
5	Platelet, Plasma, RBC + Auto PAS Set
	Spectra Optia Apheresis System
. <u>_</u> _	Spectra Optia Apheresis System Exchange Set
2	<u> </u>
2	Exchange Set
- ~	Exchange Set Collection Set

Adrienne Hammond Regulatory Affairs Manager

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To, All India Institute of Medical Sciences, New Delhi. Date: 09-06-2022

<u>Subject: Authorization Letter to M/s AVN Healthcare for the supply of Spectra Optia Platelet Plasma Set (10408)</u>

Dear Sir/Madam,

This is to certify that **M/s AVN Healthcare** Authorized Business Associate in Delhi for Sales and Marketing of products, manufactured and marketed by us.

They are also authorized to quote rates, procure orders, supply goods & collect payments on our behalf. The address is given below:

M/s AVN Healthcare

WZ-48A, Opposite M-Block, Near DDA Market,

Shakurpur, Delhi-110034

Contact Person: Mr. Anil Yadáv (Mobile: 9810876086)

You may contact concerned person mentioned above for all your queries at above mentioned address.

This Authorization letter is valid till 31st March, 2023.

Please note that this authority restricts its right to M/s AVN Healthcare and they are not authorized to provide any authorization further. This authority restricts its right <u>for the supply of Spectra Optia Platelet Plasma Set (10400)</u>.

Terumo Penpol Pvt Ltd reserves the right to change 8usiness associate/distributor during ARC with prior 15 days notice.

Thanking you,

For TERUMO PENPOL PVT. LTD.

Authorized Signatory

Mr. Panduraj Tungenwar Senior Regional Manager – West & North India

Mobile-99670 31942

TERUMO PENPOL PRIVATE LIMITED, CIN: U33112KL1935FTC004531, E-Mail: Penpulinfo@fenunobet.com

Segistered Office

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Medikad Systems Group: T.L. IIIIT, Andres Bulkings, General Happital Room, Attornesseniispigean –525 (25 Kerola, India, Pinang, 191 411, 7 1850)

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