

अखिलभारतीयआयुर्विज्ञानसंस्थान, रायपुर(छत्तीसगढ़) All India Institute of Medical Sciences, Raipur (Chhattisgarh) Tatibandh, GE Road, Raipur-492 099 (CG)

www.aiimsraipur.edu.in

AIIMS/R/HS/CSSD/2025/PAC/ 3736

Date: 26/06/2025

NOC

Sub: - Inviting Comments/Objection (if any) Regarding Procurement of Rapid biological Indicator of Steam, ETO & Plasma sterilization process for Department of CSSD at AIIMS, Raipur under Proprietary Article.

Department of CSSD, AIIMS Raipur has requirement of the Rapid biological Indicator of Steam, ETO & Plasma sterilization process, Proprietary Article basis under GFR-166.

The above documents are being uploaded for open information to submit objections/comments (if any) from any manufacturer/supplier before declaring Proprietary Article of the said equipment/items to be procured. Objections/comments to be submitted within 07 days (i.e. 4/7/2025) 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 Stores Office (Hospital), Gate no. 1, First floor Hospital Administration Block, AIIMS Raipur, Tatibandh, Raipur (C.G) Pin-492099 in a sealed envelope or through email on storesofficer.hp@aiimsraipur.edu.in with above reference on or before 4/7/2025 up to 03:00PM from the date of uploading on institutional website, failing which it will be presumed that any other manufacturer/vendor is having no comment to offer and case will be decided on merits.

Officer In-charge Procurement (DMC)
AIIMS, Raipur (C.G)

Encl:-

1. PAC letter by concerned department.

2. Proprietary & Authorization Letter by Manufacturer.

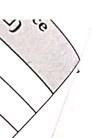
(Officer In-charge, Procurement of Drugs, Medicine & Consumable)

AIIMS, Raipur (C.G.)

Single Bid Notice Inviting Tender of Rapid biological Indicator of Steam, ETO & Plasma sterilization process for Department of CSSD under PAC at AIIMS Raipur

Sno.	Name of Item	Brand	Qty.
1.	SUPER RAPID B.I(STEAM):-	C S CHARLES	SE JERNOUS VAL
	Rapid readout biological indicators for steam sterilization containing a standardized, viable population of Bacillus stearothermophilus spores.		
	The indicator detects the presence of viable spores within 9 to 24 mins in conjunction with Super Rapid Readout Incubator.	3M 1492V	
	Designed and certified as per ISO 11138 and EN 866.	Super Rapid BI	2000 Nos.
	• Should be compatible with the pre Vacuum cycle of 132°C to 135°C Should be compliant to ISO 11138-1:2006(en) Part 1 and ISO 11138-1:2006(en) Part 3	Tarren processiff Tarren processiff unid sur shorter	
	Every box should contain Quality Assurance certificate with mention of Spore population, D-value & Z value.	ne tropolaneumani propid Caroni ema a Hyspatharona berara	
	Should have a BSI Kitemark Certificate.	yak ir basasas a	
	Should have FDA Approved.	144	
2.	SUPER RAPID B.I(PLASMA):-		
Bone de la constant d	Rapid readout biological indicators for vaporized hydrogen peroxide sterilization containing a standardized, viable population of Bacillus stearothermophilus spores	of their selections of ATTA of out to their	
	The indicator detects the presence of viable spores within 9 to 24 mins in conjunction with Rapid Readout Incubator	3M 1294 Rapid Biological	200 Nos.
	• Designed and certified as per ISO 11138 and EN 866.	Indicator	
	• Should be compatible with Amsco® VPRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), and in STERRAD® 100S, STERRAD NX (Standard and Advanced cycles) and 100ONX (Standard, Flex, Express and Duo cycles) systems.	gregoli hum ma	energia L'Accietter by
	• It should be USFDA approved and Compatible ISO 11138-1:2006(en) Part 1 and ISO 11138-1:2006(en) Part 2	ZX FORDERA (ZMILI)	as visitaings vit
	• Every box should contain Quality Assurance certificate with mention of Spore population, D-value & Z value		
3.	SUPER RAPID B.I(ETO):-		

 Rapid readout biological indicators containing a standardized, viable population of Bacillus Atropheus spores for ETO Sterilization Cycles 		
 The indicator detects the presence of viable spores by the production of fluorescence within 1 to 3 hours in conjunction with Rapid Readout Incubator. 	3M 1295 Plasma Bl	1700 Nos.
 Designed and certified as per ISO 11138 and EN 866. 		
• Should be compliant to ISO 11138-1:2006(en) Part 1 and ISO 11138-1:2006(en) Part 2		
• Every box should contain Quality Assurance certificate with mention of Spore population, D-value & Z value.		
It should be USFDA approved		





अखिल भारतीय आयुर्विज्ञान संस्थान रायपुर (छ. ग.)

All India Institute of Medical Sciences, Raipur (Chhattisgarh)

Tatibandh, GE Road, Raipur-492 099 (CG) www.aiimsraipur.edu.in

स्वामित्वप्रमाणपत्र

Proprietary Article Certificate

फाइल संख्या और।	मन्दर्भ	
File Nu	mber and Reference	
1	सामाग्रीकाविवरण Description of article	3M Super Rapid Biological Indicator of 1492V, 1295 & 1294
2	पुर्वानुमानितमात्रा/वार्षिकआवश्यकता Forecast of quantity/annual requirement	Quantity-2000, 200 & 1700 Nos. for Steam, Plasma & ETO respectively.
3	उपरोक्तमात्रा हेतुअनुमानितमूल्य Approximate estimated value for above	I.
4	निर्माता का नाम एवं पता Maker's name and address	3M Health Care, 2510 Conway Avenue St. Paul, MN 55144-1000 U.S.A.
5	अधिकृतडीलर/स्टाकिस्ट का नाम Name(s) of authorized dealers/stockiest	M/S Rose Enterprises
6	मैपी ए सी के आधारपरउपरोक्त खरीद को स्वीकारकर्ता करता हु और यह प्रमाणित करता हू कि नोट-(बी),(सी-1) या (सी-2) मे से केवल एक को बनाए रखने के लिए टिक करे, जो भी लागू हो और दूसरों को काट दे कृपया (ए) टिकत पृष्टी करे इसके बिना पी ए सी प्रमाणपत्र अवैध होगा 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) v others. Please do confirm (a) by ticking it — without which I	whichever is applicable and cross out PAC certificate will be invalid.
6 (a)	यह एकमात्र फर्म है जो इस मद का निर्माण/संग्रहण कर रहा है p This is the only firm who is manufacturing /stocking this item. AND	Yes
6 (b)	किसी अन्य फर्म द्वारा संमरूपमदनिर्मित/विक्रय नहीं किया जाता है, जिसका उपयोग इसके बदले किया जा सक्ता है अथवा A similar article in not manufacturing/sold by any other firm, which could be used in lieu OR	Yes
6 (c-1)	कोई अन्य मेच/ब्रांड निम्नितिखत कारणो (जैसे ओईएए/वारंटी के) लिए उपयुक्त नहीं होगा अथवा No other make/brand will be suitable for following tangible reasons (like OEM/warranty spares): OR	Yes

कोई अन्य मेक / ब्रांड निम्नितिखित कारणों से उपयुक्त नहीं होगा (अगर पी ए सी पिछले खरीद में भी दिया गया था, तो कृपया इसके बाद सी अधिक स्रोतों का पता लगाने के लिए प्रयाश करें) 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					
iplete par thin 15 to	aperless to 24 mir	with las nutes by	t 1000 an		
ग द्वारा की जाएगी o the prop ent)	_{एगी)} oposal (A	etion			
			(Motion		(Action

पिछले तीन सालो में इस समय की पी ए सी खरीद का इतिहास निचे PAC purchase of this item for past t		•	y)
प्रदायक का नाम Name of the Supplier			
ं आदेश / निविदा सन्दर्भ और दिनांक Order/Tender reference & Date	आदेशित मात्रा Quantity Ordered	आदेश पर मूल दर Basic Rate on order (□)	प्रतिकूल प्रदर्शन रिपोर्ट अगर कोई हो Adverse Performance Reported if any

General Guidelines

- 1. The indenting person should be In-charge/officer/faculty of the department and the Purchase Proposal Request form [PPRF] must are 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. <u>Specification must be generalize manner/nature which will be widely applicable to the manufactures.</u>
- **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).

3M Company 2510 Comway Ave. 8t, Paul, MN 55144 U.S.A.



PROPRIETARY STATEMENT

To whom it may concern,

I, Brian Kleiber, Regulatory Affairs Senior Associate, as the Authorized Signatory for 3M Company, hereby certify that the 3MTM AttestTM 390, 390G, 490, and 490M Auto-readers are proprietary products of 3M and 3M is the exclusive design owner of said products.

The 3MTM AttestTM Auto-reader 390 is designed to incubate and automatically read the 3M AttestTM Rapid Readout Biological Indicators for Steam, 1291 and 1292, at 60°C for a final fluorescent readout at 1 hour for 1291 and 3 hours for 1292.

The 3MTM AttestTM Auto=reader 390G is designed to incubate and automatically read the 3M AttestTM Rapid Readout Biological Indicators for Ethylene Oxide, 1294, at 37°C for a final fluorescent readout at 4 hours.

The 3MTM AttestTM Auto-reader 490 having software version 4.0.0 or greater is designed to incubate and automatically read 3MTM AttestTM Super Rapid Readout Biological Indicators 1491 and 1492V and 3MTM AttestTM Rapid Readout Biological Indicator 1295 at 60°C for a final fluorescence reading at 24 minutes.

The 3MTM AttestTM Mini Auto-reader 490M is designed to incubate and automatically read 3MTM AttestTM Biological Indicators 1295, 1491, and 1492V at 60°C for a final negative fluorescence reading at 24 minutes.

Document by:		,
Brian bleiber	6/20/2024	
Brian Kleiber Senior Regulatory Affairs Specialist	Date	and the second second
Medical Surgical (MedSurg) Business		

Den.

3M Health Care 2510 Conway Ave., Bldg. 275-5W-06 St. Paul, MN 55144 U.S.A 651 733 1110



311

State of Minnesota) County of Ramsey) ss

Subscribed and sworn to before me this 20 day of 10ne 2024.

Lusee R. Hang, Notary Public

My Commission Expires: January 31st, 2028



3M Science. Applied to Life."

To,

Executive Director,

AIIMS Hospital

Ralpur, (C.G)

Subject: Authorization Letter for 3M Biological Indicator for Steam/ Ethylene Oxide (EO)/Plasma Sterilization.

Respected Sir/Mam,

Supply will be through Our authorized distributor for "Biological Indicator" given below -

M/s Rose Enterprises - Shop No. 232, Aushadi Vatika, Dumartarai, Raipur C.G - 492015 .

Contact No-9922402718

Email - spsahu@mmm.com

Thanks & Regards

Science.
Applied to Life."
Santosh Sahu

Senior Sales Analyst Mobile: +91 9922402718 Email: <u>spsahu@mmm.com</u>

Ben.