



अखिलभारतीयआयुर्विज्ञानसंस्थान, रायपुर(छत्तीसगढ़)  
All India Institute of Medical Sciences, Raipur (Chhattisgarh)  
Tatibandh, GE Road,  
Raipur-492 099 (CG)  
[www.aiimsraipur.edu.in](http://www.aiimsraipur.edu.in)

AIIMS/R/HS/OBS/URO/166/2022

Date: 10/11/2022

**Call for Objections**

**Sub:- Inviting Comments/objections (if any), before declaring proprietary article for procurement of “Consumables for Plasma Sterilization System (Sterrad System)” for Various Departments at AIIMS Raipur.**

Various Departments at AIIMS Raipur has to procure consumables for Plasma Sterilization System (Sterrad System) through Proprietary Article basis under GFR -166.

The proposal submitted by M/s Advanced Sterilization Products, USA who is sole manufacturers and M/s Bagree Enterprises, Raipur is the local Agent of this item along with Proprietary Article Certificate are attached and same upload on AIIMS Raipur website.


The above documents are being uploaded for open information to submit objections/comments (if any) from any manufacturer/supplier before declaring proprietary article for the said equipment/items to be procured, within 11 days (i.e. 21/11/2022) from the date of issuance/uploading of the notifications.

The objection should be raised on 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), Room No. 329, C C1 Block, Gate No. 01, AIIMS, Raipur in sealed envelope or through mail [storesofficer.hp@aiimsraipur.edu.in](mailto:storesofficer.hp@aiimsraipur.edu.in) on or before 21/11/2022 up to 3.00 PM failing which it will be presumed that any other vendor having no comments to offer and case will be decided on merits.

**Encl:-**

1. Proprietary Letter by Manufacturer
2. Proprietary Letter by Department
3. Authentication letter of vendor

  
Stores Officer- H  
AIIMS Raipur  
भंडार अधिकारी (जस्प.)  
Store Officer (H)  
एम्स, रायपुर (छ.ग.)  
AIIMS, Raipur (C.G)



10

स्वामित्व प्रमाण-पत्र  
Proprietary Article Certificate

फाइल संख्या और संदर्भ File Number and Reference		
1	सामाग्री का विवरण Description of article	Sterrad Cassette – 25 cycles + Tyvek Roll 4" x 70 Mtr. – 6 Rolls Sterrad Cassette – 25 cycles + Tyvek Roll 6" x 70 Mtr. – 4 Rolls Sterrad Cassette – 25 cycles + Tyvek Roll 8" x 70 Mtr. – 4 Rolls Sterrad Cassette – 25 cycles + Tyvek Roll 10" x 70 Mtr. – 4 Rolls Chemical Indicator Strip (box of 1000 strips) Chemical Indicator Tape (box of 6 rolls) Biological Indicator (Box of 30 biological indicators)
2	पूर्वानुमानित मात्रा/वार्षिक आवश्यकता Forecast of quantity/annual requirement	
3	उपरोक्त मात्रा हेतु अनुमानित मूल्य Approximate estimated value for above	
4	निर्माता का नाम एवं पता Maker's name and address	ASP (Advanced Sterilization Products) India Pvt. Ltd.
5	अधिकृत डीलर/स्टाकिस्ट का नाम Name(s) of authorised dealers/stockists	M/s Bagree Enterprises, Raipur (C.G.)
6	मैं पीएसी के आधार पर उपरोक्त खरीद को स्वीकार करता हूँ और यह प्रमाणित करता हूँ कि: नोट- (बी), (सी-1) या (सी-2) में से केवल एक को बनाए रखने के लिए टिक करें, जो भी लागू हो और दूसरो को काट दें। कृपया (ए) टिक कर पुष्टि करें इसके बिना पीएसी प्रमाण पत्र 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) whichever is applicable and cross out others. Please do confirm (a) by ticking it - without which PAC certificate will be invalid.	
6 (a)	यह एकमात्र फर्म है जो इस मद का निर्माण/संग्रहण कर रहा है। और This is the only firm who is manufacturing /stocking this item. AND	
6 (b)	किसी अन्य फर्म द्वारा समरूप मद निर्मित/विक्रय नहीं किया जाता है, जिसका उपयोग इसके बदले किया जा सकता है। अथवा A similar article is not manufacturing/sold by any other firm, which could be used in lieu OR	

*Sankh*

6 (c-1)	कोई अन्य मेक/ब्रांड निम्नलिखित कारणों (जैसे ओईएम/वारंटी के) के लिए उपयुक्त नहीं होगा। अथवा No other make/brand will be suitable for following tangible reasons (like OEM/warranty spares): OR		
	<i>other make brand will not compatible with existing equipment in the department - ✓</i>		
6 (c)	कोई अन्य मेक/ब्रांड निम्नलिखित कारणों से उपयुक्त नहीं होगा (अगर पीएसी पिछले खरीद में भी दिया गया था, तो कृपया इसके बाद से अधिक स्रोतों का पता लगाने के लिए प्रयास करें) तथा 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		
	..... .....		
	प्रस्ताव के लिए वित्त शाखा की सहमति का संदर्भ (कार्रवाई भंडार और लेखाविभाग द्वारा की जायेगी) Reference of concurrence of finance wing to the proposal (Action will be taken by stores & Account Department)		
पिछले तीन सालों में इस मद की पीएसी खरीद का इतिहास नीचे दिया जा सकता है (यदि कोई हो) History of PAC purchase of this item for past three years may be given below (if any)			
प्रदायक का नाम Name of the Supplier	प		
आदेश/निविदा संदर्भ 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

अनुमोदन करने वाले प्राधिकारी का हस्ताक्षर.....

दिनांक.....

अधिकारी का पदनाम.....

*Saurabh*  
4/5/24

## TENDER SPECIFICATIONS FOR STERILANT, PACKAGING ROLLS & INDICATORS FOR STERRAD

### STERILANT FOR STERRAD® NX:

- Sterilant (H<sub>2</sub>O<sub>2</sub>) hydrogen peroxide cassette compatible with STERRAD NX with Leak Indicator on the sterilant/cassette. Each box should come with 5 cassettes and each cassette should be capable of performing 5 sterilization cycles.

### PACKAGING ROLLS:

- STERRAD NX Cassette + Tyvek Rolls bundle (details as below) with Tyvek Rolls having inbuilt chemical indicator intended to be used to enclosed medical devices that are to be terminally sterilized in the plasma/ Sterrad system should be endorsed by USFDA/510K / European CE/BIS. Pouch roll of grade **4057B** should be provided with three independent barriers. It should also be certified by ISO 9001 and ISO 13485:2016.
- Seal strength test, microbial barrier properties, burst test and peel open test should demonstrated acceptable material compatibility characteristics of the Pouches/Rolls after processing in the plasma sterilizer, also sterilant penetration and package integrity validated and endorsed by USFDA/510K / European CE/BIS.
- The pouch roll should maintain sterility for 12 months post processing in plasma sterilizer validated and endorsed by USFDA/510K / European CE/BIS.

S. No.	Item Description	Pack Size / Unit
01	STERRAD NX Cassette + Tyvek Roll 4" x 70 Mtr.	25 cycles + 6 Rolls
02	STERRAD NX Cassette + Tyvek Roll 6" x 70 Mtr.	25 cycles + 4 Rolls
03	STERRAD NX Cassette + Tyvek Roll 8" x 70 Mtr.	25 cycles + 4 Rolls
04	STERRAD NX Cassette + Tyvek Roll 10" x 70 Mtr.	25 cycles + 4 Rolls

### Chemical Indicator Strip For STERRAD NX Plasma Sterilizer:

- Chemical Indicator tape on exposure of hydrogen peroxide post sterilization should result in recognizable color change from red to yellow. The product has to be endorsed by USFDA/510K or European CE.
- Each box should come with 1000 strips.

### Chemical Indicator Tape For STERRAD NX Plasma Sterilizer:

- Chemical Indicator tape on exposure of hydrogen peroxide post sterilization result in recognizable color change from red to yellow. Adhesive strength studies should confirm that the tape has adequate preprocessing and post-processing adhesive properties to support and extension of the product to 22 months. This should be endorsed by USFDA/510k or European CE.
- Each box should come with 6 rolls of 55 meters each

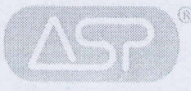
25

**Biological Indicator For STERRAD NX Plasma Sterilizer:**

- Biological indicator with fluorescence abstract technology able to give results in 15 to 30 min. Should have chemical indicator on top for Biological Indicator(BI) confirmation with barcode/QR code for Identification and tracking. The BI Should be Compatible with STERRAD NX and STERRAD Velocity Reader. Resistance characteristics of Biological Indicator - Tested at 5 mg/L hydrogen peroxide; D-value 5mg/L:  $\geq 1$  second, using two D-value methods (Survivor Curve and Fraction Negative) per ISO 11138-1 which should be endorsed by USFDA/510K or European CE.
- Each box should come with 30 Biological Indicator




24



To whom it may concern:

This letter serves to declare that the attached document is the original document produced for Advanced Sterilization Products.

For and on behalf of Advanced Sterilization Products,

  
\_\_\_\_\_  
Charlemagne Chua

Date 30 OCTOBER 2020

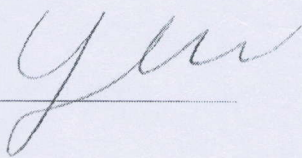
A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document, to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

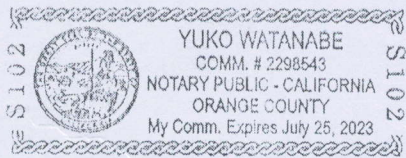
State of California  
County of Orange

On Oct. 30th, 2020, before me, Yuko Watanabe, Notary Public, personally appeared Charlemagne Chua who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that she executed the same in her authorized capacity, and that by her signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under Penalty of Perjury under the laws of the State of California that the foregoing paragraph is true and correct.

Witness my hand and official seal.

Signature 



23

**Proprietary Certificate & Agreement Representation**

**To Whomsoever It May Concern**

We, Advanced Sterilization Products (ASP) located at 33 Technology Drive, Irvine California 92618, USA, hereby certify that we are the sole legal manufacturer of the proprietary products bearing trademarks listed in Annexure A.

We further certify that Advanced Sterilization Products India Private Limited with office at FF-A-07 on First Floor of Art Guild House, LBS Marg, Kurla (West) Mumbai- 400 070 [A 100% Subsidiary of Advanced Sterilization Products (ASP) located at 33 Technology Drive, Irvine California 92618, USA,] is authorized to market the products in India. Advanced Sterilization Products India Private Limited are authorized to submit offers and commit, sign, finalize, execute orders and to appoint distributors, dealers and liaison agents for selling the complete range of products on our behalf along with providing service, consumables, spares and technical updates.

**Annexure A**

Sr. No.	Product Code	Product Name	PRODUCT DESCRIPTION
1	10113	STERRAD® 100S CASSETTE	STERILIAN FOR STERRAD® 100S
2	10133	STERRAD® NX CASSETTE	STERILIAN FOR STERRAD® NX
3	10144	STERRAD® 100NX CASSETTE	STERILIAN FOR STERRAD® 100NX
4	12320	TYVEK® POUCH 3X8IN	SELF SEAL POUCH 75 X 200 MM
5	12326	TYVEK® POUCH 4X10.25IN	SELF SEAL POUCH 100 X 260 MM
6	12332	TYVEK® POUCH 6X12.5IN	SELF SEAL POUCH 150 X 320 MM
7	12335	TYVEK® POUCH 4X14IN	SELF SEAL POUCH 100 X 350 MM
8	12340	TYVEK® POUCH 8X16IN	SELF SEAL POUCH 200 X 400 MM
9	12342	TYVEK® POUCH 6X16.5IN	SELF SEAL POUCH 150 X 420 MM
10	12348	TYVEK® POUCH 10X19IN	SELF SEAL POUCH 250 X 480 MM
11	12356	TYVEK® POUCH 12.5X22IN	SELF SEAL POUCH 320 X 560 MM
12	12407	TYVEK® ROLL 3IN X 228 FT	POUCH ROLL 75MM X 70 MM
13	12410	TYVEK® ROLL 4IN X 228FT	POUCH ROLL 100 MM X 70 M
14	12415	TYVEK® ROLL 6IN X 228FT	POUCH ROLL 150 MM X 70 M
15	12420	TYVEK® ROLL 8IN X 228FT	POUCH ROLL 200 MM X 70 M
16	12425	TYVEK® ROLL 10IN X 228FT	POUCH ROLL 250 MM X 70 M
17	12435	TYVEK® ROLL 14IN X 228FT	POUCH ROLL 350 MM X 70 M
18	12442	TYVEK® ROLL 16.5IN X 228FT	POUCH ROLL 420 MM X 70 M
19	12450	TYVEK® ROLL 20IN X 228FT	POUCH ROLL 500 MM X 70 M
20	13826	APTIMAX® TRAY	12" X 4" X 2" (305 x 102 x 51)mm
21	13827	APTIMAX® TRAY	18" X 4" X 2" (457 x 102 x 51)mm
22	13828	APTIMAX® TRAY	24" X 4" X 2" (610 x 102 x 51)mm
23	13829	APTIMAX® TRAY	12" X 8" X 2" (305 x 203 x 51)mm

22

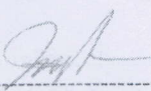
24	13830	APTIMAX® TRAY	18" X 8" X 2"(457 x 203 x 51)mm
25	13831	APTIMAX® TRAY	24" X 8" X 2" (610 x 203 x 51)mm
26	13832	APTIMAX® TRAY	7" X 3" X 1.2" (178 x 76 x 31)mm
27	13833	APTIMAX® TRAY	10" X 6" X 1.2" (254 x 152 x 31)mm
28	13834	APTIMAX® TRAY	15" X 6" X 1.2" (381 x 152 x 31)mm
29	13835	APTIMAX® TRAY	15" X 10" X 1.2" (381 x 254 x 31)mm
30	13836	APTIMAX® TRAY	11" X 10.6" X 4" (279 x 254 x 102)mm
31	13837	APTIMAX® TRAY	23" X 11" X 4" (584 x 279 x 102)mm
32	13838	APTIMAX® TRAY	24" X 13" X 4" (610 x 330 x 102)mm
33	99205	Tray Mat - SILICON MAT	6.5" x 2.5" (165 x 64)mm fits tray 13832
34	99206	Tray Mat - SILICON MAT	9" x 5.5" (229 x 140)mm fits tray 13833
35	99207	Tray Mat - SILICON MAT	14" x 5.5" (356 x 140)mm fits tray 13834
36	99208	Tray Mat - SILICON MAT	14" x 9.5" (356 x 241)mm fits tray 13835
37	99209	Tray Mat - SILICON MAT	11" x 7.5" (279 x 191)mm fits tray 13829
38	99210	Tray Mat - SILICON MAT	17" x 7.5" (432 x 191)mm fits tray 13830
39	99211	Tray Mat - SILICON MAT	23" x 7.5" (584 x 191)mm fits tray 13831
40	99212	Tray Mat - SILICON MAT	10" x 10" (254 x 254)mm fits tray 13836
41	99213	Tray Mat - SILICON MAT	21.5" x 10" (546 x 254)mm fits tray 13837
42	99400	ENDOSCOPE HOLDER	0.4" x 0.8" x 0.4 (10 x 19 x 10)mm
43	99401	ENDOSCOPE HOLDER	0.8" x 0.4" x 0.8" (19 x 10 x 19)mm
44	99402	ENDOSCOPE HOLDER	0.2" x 0.8" x 0.2" (5 x 19 x 5)mm
45	99403	ENDOSCOPE HOLDER	0.8" x 0.2" x 0.8" (19 x 5 x 19)mm
46	99404	ENDOSCOPE HOLDER	0.4" x 0.4" x 0.4" (10 x 10 x 10)mm
47	99405	ENDOSCOPE HOLDER	0.6" x 0.6" x 0.6" (15 x 15 x 15)mm
48	99406	ENDOSCOPE HOLDER	0.2" x 0.2" x 0.2" (5 x 5 x 5)mm
49	99407	HOLDING BAR FOR INST TRAY	Holding bar FO" inst " inst 2 shelf packs
✓ 50	14100	CHEM INDICATOR STRIP	CHEM INDICATOR STRIP
✓ 51	14202	SEALSURE CI TAPE	CHEMICAL INDICATOR TAPE
✓ 52	14324	CYCLESURE® 24 BIO INDICATOR	CYCLESURE® 24 BIO INDICATOR
✓ 53	43210-30-14	STERRAD® Velocity Biological Indicator	STERRAD® Velocity Biological Indicator
54	21006	INCUBATOR 230V	INCUBATOR 230V
55	15400-020	STERRAD BOOSTER	STERRAD BOOSTER
56	15401	BOOSTER ADPTR I 50/CS	BOOSTER ADPTR I 50/CS
57	15402	BOOSTER ADPTR II 50/CS	BOOSTER ADPTR II 50/CS




21

58	15403	BOOSTER ADPTR III 50/CS	BOOSTER ADPTR III 50/CS
59	10305	THRML PRNTR PPR RLS-12/CS	FOR STERRAD® NX
60	40-03174-001	RIBBON CARTRIDGE RED/BLK	FOR STERRAD® 100S
61	40-03175-002	PAPER PRINTER TWO PLY	FOR STERRAD® 100S
62	10306	CASSETT DISP BOX NX	CASSETTE DISPOSAL BOX FOR STERRAD® NX
63	20227	CASSETTE DISPOSAL BOX KIT	CASSETTE DISPOSAL BOX FOR STERRAD® 100NX
64	20224	STERRAD® 100S Accessory Kit	PRINTER PAPER,RIBBIN,CARTRIDGES,CASSETTE COLLECTION BOX,VAPORIZER PLATES
65	10134	100NX EXPRESS CYCLE KIT	100NX EXPRESS CYCLE KIT
66	10308	BARCODE READER	BARCODE READER
67	43221	PRINTER, VELOCITY	PRINTER, VELOCITY
68	10033	STERRAD NX	STERRAD NX
69	10033004	STERRAD NX WITH ALLCLEAR	STERRAD NX WITH ALLCLEAR
70	10101	STERRAD 100S STERILIZER	STERRAD 100S STERILIZER
71	10104	STERRAD(R) 100NX(TM) 1-DR	STERRAD(R) 100NX(TM) 1-DR
72	10104002	STERRAD(R) 100NX(TM) 2-DR	STERRAD(R) 100NX(TM) 2-DR
73	10104005	ST100NX ALLCLEAR 1-DR	ST100NX ALLCLEAR 1-DR
74	10104006	ST100NX ALLCLEAR 2-DR	ST100NX ALLCLEAR 2-DR
75	10311	STERRAD NX SYSTEM CART	STERRAD NX SYSTEM CART
76	43220	Velocity Reader	Velocity Reader
77	53001	ASP ACCESS	ASP ACCESS

Signed on behalf of Advanced Sterilization Products

  
 -----  
 Charlemagne Chua  
 Sr. Regulatory Affairs Manager

Date 30 OCTOBER 2020 

Authorization letter

13<sup>th</sup> April 2022

To,  
The Director,  
AIIMS, Raipur.

Dear Sir/Madam,

We are authorizing **M/s. BAGREE ENTERPRISE, Raipur** located at below address to quote Advanced Sterilization Products India Pvt. Ltd., products manufactured and marketed by us.

**M/s. Bagree Enterprises,  
Near City Kotwali,  
Chotapara, Raipur -492001  
Mob. +91 9329102116**

We authorize them to quote rates, raise bills and collect orders & payments on our behalf to your institute. M/s. BAGREE ENTERPRISES, Raipur are authorized to bid, negotiate, and conclude the contract regarding this business in your hospital.

We authorize them to quote rates, raise bills and collect orders & payments on our behalf.

- Validity of the letter will be 1 year from date of issuance

Yours Truly,



**For Advanced Sterilization Products India Pvt. Ltd.  
Vivek Suryawanshi  
Regional Sales Manager – West  
Email: vivek.suryawanshi@asp.com  
Cell : 9823354400**