



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/BME//2024/PAC/ 12643

Date: 03/01/2024

**Call for Objections**

**Sub:- Inviting Comments/objections (if any), regarding procurement of Aerogen Solo Nebuliser with T-Piece for our existing C3 Ventilators installed at various ward and OT in hospital area at AIIMS Raipur under Proprietary Article Basis.**

Bio Medical Engineering Department, AIIMS Raipur has to procure the **Aerogen Solo Nebuliser with T-Piece for our existing C3 Ventilators installed at various ward and OTs area** through Proprietary Article Basis under GFR -166. The proposal submitted by **M/s Aerogen Ltd. located at Galway Business Park Dangan, Galway H91 HE94, Co., Galway Ireland.** who is sole manufacturer 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 **10 days** 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 speedpost before 12/01/2024 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

*A. Ramana*  
Stores Officer- H  
AIIMS Raipur  
मंडार अधिकारी (अस्प.)  
Store Officer (H)  
एम्स, रायपुर (छ.ग.)  
AIIMS, Raipur (C.G.)



अखिल भारतीय आयुर्विज्ञान संस्थान, रायपुर (छत्तीसगढ़)  
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2023

स्वामित्व प्रमाण पत्र  
Proprietary Article Certificate

फाइल संख्या और संदर्भ File Number and Reference		
1	सामाग्री का विवरण Description of article	1. Aerogen Solo Nebuliser With T-Piece (Pack of 10)
2	पूर्वानुमानित मात्रा Forecast of quantity/annual requirement	As Per PPRF
3	उपरोक्त मात्रा हेतु अनुमानित मूल्य Approximate estimated value for above	As Per PPRF
4	निर्माता का नाम एवं पता Maker's name and address	M/s Aerogen Ltd. located at Galway Business Park Dangan, Galway H91 HE94, Co. Galway Ireland.
5	अधिकृत डीलर/स्टाकिस्ट का नाम Name(s) of authorised dealers/stockists	M/s Bagree Enterprise, Ground and 1 <sup>st</sup> C/236/35/405, Behind Zudio Clothing Centre Shailendra Nagar, Raipur, CG -492001
6	मैं पी ए सी 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 एक मात्र फर्म है जो इस मद का निर्माण/संग्रहण कर रहा है। और This is the only firm who is manufacturing /stocking this item. AND	Yes
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	

(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	
	.....	
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 लेखा विभाग 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	आदेशित मात्रा Quantity Ordered	आदेश पर मूलदर (₹) Basic Rate on order (₹)	प्रतिकूल प्रदर्शन रिपोर्ट अगर कोई हो Adverse Performance Reported if any
आदेश/निविदा संदर्भ और दिनांक Order/Tender reference & Date			

अनुमोदन करने वाले प्राधिकारी का हस्ताक्षर.....

Dr. Dibakar Saini

उप-निदेशक अधीक्षक  
Dy. Medical Superintendent

ऑल इंडिया मेडिकल साइंसेस संस्थान, रायपुर (C.G.)  
All India Institute of Medical Sciences, Raipur (C.G.)

Ref.: Aerogen/WR/125  
Date: 12/05/2023

To  
The Director of AIIMS, Raipur  
Great Eastern Rd, opposite Gurudwara,  
AIIMS Campus, Tatibandh, Raipur,  
Chhattisgarh 492099

### Letter of Authorization

We, Aerogen Medical Devices India Pvt Ltd, are a wholly owned subsidiary of M/s Aerogen Ltd, a manufacturer of Pro/Pro X / USB Controllers and Solo/ Pro Nebulizer and associated components with its registered office Galway Business Park, Dangan, Galway, Country: Ireland and a manufacturing facility located at M & M Qualtech Ltd, Parkmore Business Park West, Ballybrit, Co. Galway, Country: Ireland.

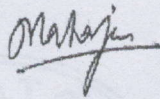
We hereby confirm BAGREE ENTERPRISE, Ground and 1st, C/236/35/405, BEHIND ZUDIO CLOTHING CENTRE, SHAIENDRA NAGAR, Raipur, Chhattisgarh, 492001 is an authorized distributor of the following Aerogen products for supplying in your institute.

1. Pro Controller
2. Pro X Controller
3. USB Controllers
4. Solo and Pro Nebulizer and associated components

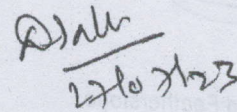
BAGREE ENTERPRISE is authorized to Quote for the above said products, effect supplies and collect payments.

This letter of authorization is valid for twelve (12 months) from the date stated above unless earlier revoked by Aerogen Medical Devices India Pvt Ltd at its sole discretion.

### Authorised Signatory




**Aerogen Medical Devices India Pvt Ltd.**  
Milind Mahajan  
Regional Manager -West India  
Phone +91 9967011060  
E-Mail [mmahajan@aerogen.com](mailto:mmahajan@aerogen.com)



डॉ. दिवाकर साहू  
Dr. Dibakar Sahu  
उप-सिद्धिगण प्रमुख  
By. Medical Superintendent  
ऑडिटर भारतीय आयुर्विज्ञान संस्थान, राipur (C.G.)  
All India Institute of Medical Sciences, Raipur (C.G.)  
(Valid) Date: 12/05/2023

Aerogen Medical Devices India Pvt. Ltd. 131, First Floor, ABW Rectangle Building, D4 District Centre, Saket, New Delhi -110017, Ind  
T: +91 (11) 41422577, CIN No.: U51909DL2019PTC358844, GSTIN: 07AATCA0578PIZV

Head Office: Galway Business Park, Dangan, Galway, Ireland, VAT Reg No. 8277354F Registered in Dublin, Ireland,  
Company Reg. No. 277354 E: [info@aerogen.com](mailto:info@aerogen.com) T: +353 01 584 400 F: +353 01 584 630 W: [www.aerogen.com](http://www.aerogen.com)

# Aerogen

Date: 20th May 2019

Title: Proprietary Certificate

To Whom it Concerns,


This is to certify that the Aerogen Drug Delivery System (Pro/Pro X / USB Controllers and Solo/ Pro Nebulizer and associated components) are Proprietary Products manufactured by Aerogen Ltd., located at Galway Business Park, Dangan, Galway, H91 HE94, Co. Galway, Ireland.

"Aerogen" is a registered trademark in India trademark and are also the registered service marks (included under form 10-K) having US patents and copywrites.

Aerogen Ltd. is registered under National Standards Authority of Ireland (MDSAP Recognized Auditing Organization- Certificate Number MP19.3129/Rev1)) certifying Aerogen's Quality Management System to ISO 13485:2016, to the Australia-Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure. , Brazil- RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009 , Canada- Medical Devices Regulations – Part 1- SOR 98/282 , Japan- MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable) , United States- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D, , 21 CFR 820 - Quality System Regulation, for the Design and Development and Manufacturing of Aerosol Delivery Systems for Systemic Treatment and Drug Delivery.

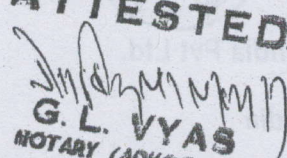
The Aerogen Ltd. products outlined above were cleared by the FDA (Food and Drug Administration) under the 510K application process. The Aerogen Ltd. products outlined above are CE marked and meet the requirements of Annex I of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC.

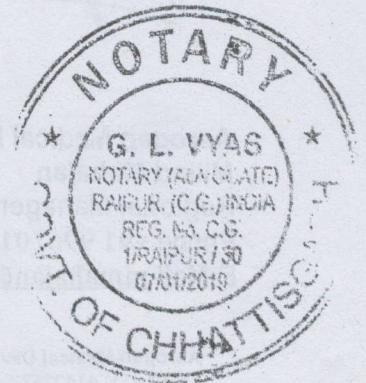
Aerogen Ltd. is the sole supplier of Aerogen Ltd. products into the global market, which includes but not limited to the Indian subcontinent market. To the best of our knowledge Aerogen Ltd. products are not manufactured by any other company/organisation globally.



Richard Featherstone  
Sales Director –Asia Pacific  
Encl- List of patents

1 JUN 2023

**ATTESTED**  
  
**G. L. VYAS**  
NOTARY (ADVOCATE)  
RAIPUR. (C.G.)



Aerogen Ltd. Galway Business Park, Dangan, Galway, Ireland  
Phone +353 91 540 400 eMail info@aerogen.com Website www.aerogen.com

**Aerogen Ultra (Pediatric):**

1. It should be specific to the Aerogen solo nebulizer for spontaneously breathing patients
2. It should be single patient use device
3. Should be able to be used with or without oxygen
4. Used with mouthpiece or valved mask for Pediatric patients
5. 20 intermittent use treatments (at a rate of four 3 mL doses per day)
6. It should be Portable.
7. Should be usable for Pediatric patients
8. Pack of 10 x Aerogen solo, Aerogen Ultra, Oxygen Tubing, I-Guard™ Aerosol Mask (Pediatric), Mouthpiece

**Aerogen USB Controller:**

1. The USB Controller system should be a microprocessor-based controller to aerosolize the drug in two intermittent modes (30 min & 6 hours) through the nebulization unit (Aerogen Solo)
2. It operates with AC/DC adapter (input 100 to 240 VAC 50 – 60 Hz, output 9V) or from a USB port on medical electrical equipment approved to IEC/EN 60601-1
3. Power Consumption is  $\leq 2.0$  Watts (while nebulizing) for portable applications
4. The AC/DC adapter is warranted against defects in manufacturing for a period of One years from the date of purchase.

**NOTE:**

1. The Product should be USFDA / EU-CE / BIS approved. Certificate to be enclosed.
2. Letter of Authorization from the OEM to be submitted along with bid.

*Dibakar*  
27/07/2022

Dr. Dibakar Sahu  
Dr. Medical Superintendent  
All India Institute of Medical Sciences, Raipur (C.G.)  
Date: ...../20.....

## Specifications For Aerogen Products

### Aerogen Solo:

1. Light weight (13.5 gm), silent single patient use nebulizer (recommended for 28 days of use)
2. Works on Vibrating Mesh Technology (Vibronic) to create uniform fine aerosol drug particle (1-5 micron) for best drug deposition in lung during treatment of neonatal to adult patients at ICU /CCU /NICU etc.
3. Suitable to aerosolize recommended drug /antibiotics/ vaccines
4. Suitable to operate with either A.C-powered controller / USB Controller
5. Suitable to be used as small volume with drug load capacity of 6 ml with ventilators / or under continuous mode through syringe pump combination/or as standalone unit with mask
6. Can be used with any ventilatory circuit, humidifier for online use and with mask/ mouth piece as Ultra combination for spontaneously breathing patients in hospital
7. Noise level: < 35 dB measured at 0.3 m distance
8. Flow rate: > 0.2 mL/min (Average ~ 0.38 mL/min)
9. Pack of 10 x Aerogen Solo and T-Piece

### Aerogen Ultra (Adult):

1. It should be specific to the Aerogen solo nebulizer for spontaneously breathing patients
2. It should be single patient use device
3. Should be able to be used with or without oxygen
4. Used with mouthpiece or valved mask for adult patients
5. 20 intermittent use treatments (at a rate of four 3 mL doses per day)
6. It should be Portable.
7. Should be usable for adults patients
8. Pack of 10 x Aerogen solo, Aerogen Ultra, Oxygen Tubing, I-Guard™ Aerosol Mask (Adult), Mouthpiece

*Dibakar Sahu*  
*27/01/2024*

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Dr. Dibakar Sahu  
Dr. Medical Superintendent  
Institute of Medical Sciences, Raipur (C.G.)