Ganesh Shankar Vidyarthi Memorial Medical College
Swaroop Nagar, Kanpur, Uttar Pradesh 208002

NO 214.

Date:- 25/07/2024

NOTICE

SUBJECT: Procurement of following item on proprietary/single source basis for GSVM Medical College, Kanpur.

The GSVM Medical College, Kanpur intends to procure following item(s) manufactured as per mentioned against item names for GSVM Medical College, Kanpur **(REC Fund)** on Proprietary/single source basis from their authorized dealer/seller as per enclosed Technical Specifications.

S.N	Equipment/Item Name	Deptt	Name of the Oem
1	Air Decontamination Unit-Plasmair	GSVM Medical College, Kanpur	M/s Airinspace, France
2	Automatic Deployable Mobile Patient Isolation Room-Rediroom	GSVM Medical College, Kanpur	M/s GAMA Healthcare Ltd.
3	4K Visualization Tower For Advance Laparoscopy Surgery	GSVM Medical College, Kanpur	M/s UnivLabs Technologies Pvt Ltd.

The Proprietary Certificate for above item(s) submitted by principal company or their Authorized Seller/ company/Dealer is attached. The above documents are being uploaded for open information to all manufacturers/suppliers to submit objection/representation, comments on the above proposal/ Proprietary/ single source nature of the equipment/item within 10 days to the Finance Office, GSVM Medical College, Kanpur, from the date mentioned above failing which it will be presumed that any other supplier is having no comment to offer and the case will be decided on merits. The comments/objections/representations to be submitted on the following:-

1. Whether the above equipment/item is manufactured by any other manufacturer other than as per mentioned principal company or their Authorized Seller/Company/Dealer.
2. Fulfill all the parameters as per technical specifications.

Note: In case the objection is not received within 10 days, the process of procurement of the said items will be done through PAC bidding/single procurement on Gem portal.

Specifications - Air Decontamination Unit

Hospital Critical Area Indoor Environment Decontamination System

- The manufacturer should have a white paper or a peer review study to prove that the unit can be used in / for neutropenic / Immune-suppressed patient care areas.
- The unit should use nonthermal – plasma reactors to reduce / lower the airborne bioburden.
- The Unit should able to provide log 2 reduction of air borne particles within 20 minutes of its operational time in a critical care area. Should have supportive documents.
- The Unit should not use of any form of gases and any chemical product consumption to reduce airborne bio burden.
- The Unit should have efficacy evidence against mycobacterium & aspergillus. Evidence should be provided.
- Device should have independent stages of processing system to remove VOC and gases.
- Prefilter should have capacity to filter up to 10 microns size particles. Supportive document should be provided.
- Designed to be used continuously, in presence of patients.
- It should be actual Mobile unit on study wheels.
- The Unit should have minimum air flow speed of 1400 m3/hr
- Supportive document should be provided to prove the machine's running speed.
- Noise level should be less than 52 db (A) even at maximum airflow speed.
- Machine should be between 5 - 6 feet height for better air circulation.
- Should have an indicator for malfunctioning.
- European CE / US FDA

Essential Criteria:

1. First 5 years equipment will be under warranty which will be covered with the cost of the equipment

2. Demonstration mandatory at hospital premises at OEM cost.

3. Training of 5 Doctors to be arranged at a center of international repute.

4. CMC offered for quoted equipment should not be more than 5% of the quoted model with not more than 5% escalation per year after completion of warranty period- 6^{th} to 10^{th} year.

5. CMC offered for the quoted equipment must be on OEM letterhead. (CMC offered on distributors/Vendor letterhead will not be considered).

6. Installation process should be performed by OEM trained service engineer/ service representative on OEM's letter head/ service report, with a mandatory provision of providing preventive service visit of OEM trained service engineer/service representative quarterly per year till completion of warranty period (i.e. 20 visit for first five years) and further quarterly visit (04 visits/ year) till the completion of CMC period.

7. The installation process must be completed by the OEM/Service provider within 30 days of supply.

8. In case of technical snag/ failure/breakdown, the response time for inspection should be within 24 hours and repair with 5 days, otherwise provide a service machine until the period of recovery of breakdown of the unit. Failing which will attract penal action as per the decision of the GSVM Medical College (Uptime guarantee of 95%).

9. All the technical specifications accepted in the compliance statement must be supported by Original Literature from the firm/O.E.M with Highlighting, Numbering and flagging it's per below mentioned format for the compliance statement

S. NO	Technical Specification	Compliance Yes/NO	Page No. in the proposal submitted where documentary evidence is enclosed as per tender Specs with highlighting Numbering & flagging

T. +33 (0)1 30 07 01 01
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contact@airinspace.com

airinspace®

AUTHORISATION LETTER

Date: 22-07-2024
To,
The Principal and Dean
Ganesh Shankar Vidyarthi Memorial Medical College
Swaroop Nagar, Kanpur, Uttar Pradesh 208002

Sub: Authorization Letter

Dear Sir,
We, M/s Airinspace, are the original manufacturers of the PLASMAIR® Guardian Mobile Air Decontamination Units, having registered office at 14 rue Jean MONNET 78990 ELANCOURT France do hereby authorise M/s Oriental Surgical Works, 1708/09, Mittal Medical Market, Gali Jai Kishan, Bhagirath Palace, Delhi, 110006, to submit Bids/Tender.

We also declare that we have the capacity to manufacture, supply, install, and commission the quantity of the bid item within the stipulated time. We ensure and extend our responsibility for quality and satisfactory supplies by our above-mentioned authorised dealer.

Best regards

Airinspace C.E.O.
Stéphane CHATENET

AIRINSPACE S.E
14, rue Jean Monnet
78990 Elancourt
FRANCE
Tél +33(0)1 30 07 01 01
www.airinspace.com
S.E au capital de 4 232 439,14€
RCS 789 460 995 - APE 7112B

airinspace®

AIR quality

MOBILE AIR DECONTAMINATION UNIT

PLASMAIR™

HEPA-MD technology | Fast | Quiet

PLASMAIR™ Guardian

- HEPA-MD technology
- Destuction of microorganisms
- Highly efficient filtration
- Chemical, VOC and Odor removal
- Very quiet

PLASMAIR™ Guardian is mobile air decontamination unit which incorporates HEPA-MD technology. The high flow rate allows treating large rooms quickly.

Use: Hematology, Bone Marrow Transplant unit, solid transplant unit, onco-hematology and pharmacy.

Related products: BIOCAIR™, IMMUNAIR™.

MOBILE AIR DECONTAMINATION UNIT

PLASMAIR™ Guardian

airinspace®

KEY FEATURES			
Power supply	~ 100 V, ~ 110/120 V, ~ 230 V		50/60 Hz
Maximum power supply	600 VA / 600 W		
Electrical protection	Isolated by removable power cable		Ph + N bipolar switch with fuses
Volumetric flow rate	Air flow continuously adjustable from 500 m³/h to 2,500 m³/h *(294 CFM to 1,471 CFM)* *(Maximum flow rate, unused pre filter)*		
Sound level as per NF-EN ISO 3744:2012 standard at 1 m / 2 m *(3.3'/6.6')* *(unused pre-filter)*	500 m³/h *(294 CFM)* - 30 dB(A) / <30 dB(A)	1,000 m³/h *(589 CFM)* - 39 dB(A) / 35 dB(A)	1,500 m³/h *(883 CFM)* - 47 dB(A) / 43 dB(A)
	2,000 m³/h *(1,177 CFM)* - 53 dB(A) / 49 dB(A)	2,500 m³/h *(1,471 CFM)* - 58 dB(A) / 54 dB(A)	
Air treatment capacity *(volume of room)*	Potentially all volumes according to desired level of efficiency		
Aerosol filtration efficiency at 1,000 m³/h *(589 CFM)* *(Unused pre-filter and reactor)*	> 99.999 %		Particles Ø ≥ 0.3 µm
Microorganisms destruction	Yes, with HEPA-MD technology		
Microbiological cleanliness class	Total flora		M10 from 18 ACH
	Fungi		M1 from 12 ACH
Particle cleanliness class	ISO 7 from 12 ACH		
Decontamination kinetic	$CP_{0.5}$12 at 15 ACH		$CP_{0.5}$7 at 30 ACH
Water/solid protection	Complete device		IP40
	Control panel		IP40
Overall dimensions	H 1,940 x L 912 x D 690 mm *(76"H x 36"L x 27"D)*		
Ground support *(Offset swivel casters)*	Small side		475 to 635 mm *(18" to 25")*
	Large side		685 to 845 mm *(27" to 34")*
Weight	191 kg *(421 lbs)*		
Maximum floor load	587 kg/m² (ground support 475 x 685 mm) / *125 psf (ground support 18"x 27")*		
Environmental operating range	Temperature		+5 °C to +35 °C *(+41°F to +95°F)*
	Relative humidity*		< 95 % non-condensing
Environmental storage range	Temperature		0 °C to 45 °C *(+32°F to +113°F)*
	Relative humidity		20 % to 90 %
	Dust level		< 1 mg/m³ *(0.03 mg/ft³)*

** During intensive wet cleaning of the installation area, it is strongly recommended to temporarily switch off the appliance to limit the peak moisture effect.*

CONTROL PANEL

1	OK	This icon indicates that the unit is working properly
2		This icon indicates a warning
3		This icon indicates an alarm
4		This icon indicates the ventilation setting: DAY/NIGHT
5		This icon indicates room flow rate and volume
6		Access key to setup menu
7		Signal that automatic night-time programmer is activated
8		Signal that manual mode is activated

Direction of the air flow in the PLASMAIR™ Guardian

airinspace®
14, rue Jean Monnet
78990 Élancourt
France

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contact@airinspace.com

French Healthcare

ORIGINE FRANCE GARANTIE BVCert. 6227600

afaq ISO 9001 Qualité AFNOR CERTIFICATION

afaq ISO 13485 Santé Médical AFNOR CERTIFICATION

www.airinspace.com

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contact@airinspace.com

airinspace®

TO WHOM IT MAY CONCERN

Sub: - Proprietary Certificate

Dear Sir/ Madam,

This letter is to confirm that the PLASMAIR™ Guardian (model T2006 G) - mobile air decontamination product is exclusively manufactured and a proprietary product of Airinspace in France.

No other company is permitted to manufacture or use the registered trademark for this equipment in any way whatsoever.

The PLASMAIR™ HEPA-MD is a patented process of particle collection, microbial destruction and removal of VOC remain the property of Airinspace under worldwide protection.

Yours faithfully,
Elancourt, 20/01/2024

S. CHATENET

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S.E au capital de 4 232 439,14€
RCS 789 460 995 - APE 7112B

Certificat

Certificate

N° 2012/50082.8

AFNOR Certification certifie que le système de management mis en place par :
AFNOR Certification certifies that the management system implemented by:

AIRINSPACE

pour les activités suivantes :
for the following activities:

CONCEPTION, DEVELOPPEMENT, INDUSTRIALISATION, FABRICATION EN SOUS TRAITANCE ET COMMERCIALISATION ET MAINTENANCE DE SOLUTIONS DE DECONTAMINATION DE L'AIR ET DES SURFACES.

DESIGN, DEVELOPMENT, PRODUCTION ENGINEERING, SUBCONTRACTED MANUFACTURING, MARKETING AND SALE AND MAINTENANCE OF AIR AND SURFACE DECONTAMINATION SOLUTIONS.

a été évalué et jugé conforme aux exigences requises par :
has been assessed and found to meet the requirements of:

ISO 9001 : 2015

et est déployé sur les sites suivants :
and is developed on the following locations:

14 RUE JEAN MONNET DES BRUYERES ET DES COTES FR-78990 ELANCOURT

Ce certificat est valable à compter du (année/mois/jour)
This certificate is valid from (year/month/day) **2022-05-20**

Jusqu'au
Until **2025-04-04**

SignatureFournisseur

Julien NIZRI
Directeur Général d'AFNOR Certification
Managing Director of AFNOR Certification

Flashez ce QR Code pour vérifier la validité du certificat

Certificat

Certificate

N° 2017/74977.3

AFNOR Certification certifie que le système de management mis en place par :
AFNOR Certification certifies that the management system implemented by:

AIRINSPACE

pour les activités suivantes :
for the following activities:

CONCEPTION, DEVELOPPEMENT, INDUSTRIALISATION, FABRICATION EN SOUS TRAITANCE, COMMERCIALISATION ET MAINTENANCE D'EQUIPEMENTS DE DECONTAMINATION DE L'AIR.

DESIGN, DEVELOPMENT, PRODUCTION ENGINEERING, SUBCONTRACT MANUFACTURING, MARKETING AND SALE AND MAINTENANCE OF AIR DECONTAMINATION SOLUTIONS.

a été évalué et jugé conforme aux exigences requises par :
has been assessed and found to meet the requirements of:

ISO 13485 : 2016

et est déployé sur les sites suivants :
and is developed on the following locations:

14 RUE JEAN MONNET DES BRUYERES ET DES COTES FR-78990 ELANCOURT

Ce certificat est valable à compter du (année/mois/jour)
This certificate is valid from (year/month/day) **2022-05-20**

Jusqu'au
Until **2025-04-04**

Ce document est signé électroniquement. Il constitue un original électronique à valeur probatoire.
This document is electronically signed. It stands for an electronic original with probationary value.

Julien NIZRI
Directeur Général d'AFNOR Certification
Managing Director of AFNOR Certification

Flashez ce QR Code pour vérifier la validité du certificat

T. +33 (0)1 30 07 01 01
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contact@airinspace.com

airinspace®

EC Declaration of conformity /
Déclaration de conformité CE

Manufacturer's Name / Nom du fabricant : AIRINSPACE S.E.
Manufacturer's address / Adresse du fabricant : 14, rue Jean Monnet
78990 Elancourt,
Made in / Fabriqué en : France

Family of products / Famille de produits :	PLASMAIR™
Model / Modèle :	PLASMAIR ™ Guardian
Part code / Code produit :	**CP 21000**
Electrical network / Tension électrique :	**230 Vac +/- 10% - 50/60 Hz** **110 Vac +/- 10% - 50/60 Hz**
Clinical fields covered / Domaines d'utilisation Clinique	**Mobile air decontamination unit** Unité mobile de décontamination de l'air
Notified body for CE marking / Organisme notifié pour le marquage CE :	**Not applicable** / Sans objet

We hereby declare that the above mentioned model from family /
Nous soussignés déclarons que le modèle mentionné ci-dessus de la famille **:** PLASMAIR ™

is CE marked and meet following requirements /
dispose du marquage CE et est conforme aux directives et normes suivantes :

- **Low Voltage Directive (LVD) /** Directive européenne "Basse Tension (BT) **2014/35/UE**
  European Directive Electromagnetic Compatibility (EMC) / Directive européenne "CEM" **2014/30/UE**
- **Standard /** Norme **EN 61010-1 : January 2011 + A1:2019**
  Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements / Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 1 : exigences générales
- **Standard /** Norme **EN 61326-1 : Juin 2021**
  Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements /Matériel électrique de mesure, de commande et de laboratoire - Exigences relatives à la CEM - Partie 1 : exigences générales

Elancourt, May 2nd, 2022

Chief Executive Officer /
Directeur Général
Stéphane CHATENET

Specification Automatic Deployable Mobile Patient Isolation Room

1. It should be a quickly deployable patient isolation room with a negative airflow
2. The device should be mobile on wheels with easily lockable wheels.
3. The device should be suitable for quickly isolating suspected/confirmed infectious disease patients on the site by deploying on the wheel unit.
4. The temporary mobile single-patient room should be able to be deployed and made operational by a single person in under 5 minutes.
5. The isolation room should have easy-to-operate switches to automatically deploy sections of the room in sequence.
6. The isolation room canopy should have integrated colour-coded knobs for loading it on the system for an error-free automatic deployment of the isolation room
7. The unit should have an inbuilt negative airflow system.
8. The unit should be equipped with HEPA 14 and carbon filters to remove 99.995% of particles as small as 0.3 microns from the air.
9. The device should provide a minimum of 12 Air changes per Hour (ACH).
10. The device should have hands-free foot pedal-operated entry and exit options to limit the risk of hand and cross-contamination.
11. The Fully deployed patient room should have minimum dimensions: 210 cm Height x 275 cm Width x 340 cm Depth.
12. The room should provide enough space for an ICU Bed and required medical equipment and accessories and should provide enough space for comfortable movement action of the Doctor/caretaker
13. Opening doors should allow for a bed to be wheeled into the room using the foot-operated pedals only i.e. through hands-free operation
14. A Privacy window should be available in the room to maintain patient confidentiality and to allow caretakers to monitor the patient without entering the room.
15. The device should include an in-built PPE station to encourage Infection Prevention Compliance and provide products at the point of use.
16. The room should be made of flame-retardant material.
17. Should be easy to transport, mounted on wheels with four-foot brakes and stored.
18. Should be easy to store with Undeployed, isolation room should not exceed 140 cm Height x 75 cm Width x 80 cm Depth.
19. The device should have a facility for the travel locking pin to ensure safe transport.
20. The device's maximum noise level should not exceed 55 dBA for patient safety and comfort, evidence/document is to be provided to confirm this value.
21. The vendor should provide clinical evidence to prove that the device reduces the risks of healthcare-associated infections (HAIs).
22. The device should be classified as a Class I Medical Device.
23. The device should be ISO & European CE certified.

Essential Criteria:

1. First 5 years equipment will be under warranty which will be covered with the cost of the equipment

2. Demonstration mandatory at hospital premises at OEM cost.

3. Training of 5 Doctors to be arranged at a centre of international repute.

4. CMC offered for quoted equipment should not be more than 5% of the quoted model with not more than 5% escalation per year after completion of warranty period- 6^{th} to 10^{th} year.

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7. The installation process must be completed by the OEM/Service provider within 30 days of supply.

8. In case of technical snag/ failure/breakdown, the response time for inspection should be within 24 hours and repair with 5 days, otherwise provide a service machine until the period of recovery of breakdown of the unit. Failing which will attract penal action as per the decision of the GSVM Medical College (Uptime guarantee of 95%).

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S. NO	Technical Specification	Compliance Yes/NO	Page No. in the proposal submitted where documentary evidence is enclosed as per tender Specs with highlighting Numbering & flagging

GAMA Healthcare Ltd.,
The Maylands Building, Maylands Avenue,
Hemel Hempstead, Hertfordshire,
HP2 2TG, UK.

T +44 (0)20 7993 0034
E Helpdesk@gamahealthcare.com

Date-23-07-2024

AUTHORISATION LETTER

To,
The Principal & Dean
Ganesh Shankar Vidyarthi Memorial Medical College
Swaroop Nagar, Kanpur, Uttar Pradesh 208002

Sub: Authorization Letter

Dear Sir,

We **M/s GAMA Healthcare Limited** are the original manufacturers of the Rediroom having registered office at The **Maylands Building, Maylands Avenue, Hemel Hempstead, Hertfordshire**, **HP2 7TG** do hereby authorize **M/s. MMK Surgical Works, Address- U-74 Shop No 108, Tirupati Building, Shakarpur, Delhi, 110092** to submit Bids/Tender.

We also declare that we have the capacity to manufacture and supply, install and Commission the quantity of the Bidding item, within the stipulated time. We ensure and extend our responsibility for quality and satisfactory supplies by our above mentioned authorized dealer.

Yours faithfully,

Dr Guy Braverman
Managing Director and Co-founder
For and on behalf of GAMA Healthcare Limited

THE QUEEN'S AWARDS FOR ENTERPRISE: INTERNATIONAL TRADE 2018

DISCUSSION PIECE

Assessment of patient isolation capability.

Droplets & contaminated air

Introduction

Rediroom equips hospitals to isolate patients in a new way: by bringing isolation to them. This revolutionary design conforms to multinational guidelines[1] and is suitable for patients isolating under contact and droplet precautions.

Achieving 12 air exchanges per hour (ACH), Rediroom's integrated filtration system generates negative airflow that aids containment. Recent testing has further evidenced Rediroom's capabilities.

Abstract

The Health & Safety Executive (HSE), a government agency responsible for occupational risk, examined Rediroom's ability to effectively manage droplets and contaminated air in conditions that simulate real-world situations.

Test 1: Droplets[2]

A 'cough simulator' rapidly expelled airborne droplets, to mimic those produced by an infectious patient coughing at a standard rate[3].

Test 2: Contaminated air[4]

Smoke, used to mimic contaminated air exhaled by an infectious patient, was pumped into a Rediroom.

Results

The droplets and smoke were monitored to see if they contaminated areas outside of the Rediroom, while the doors were closed. Completely contained inside, Rediroom demonstrated that it is capable of isolating infectious patients and preventing infection by contact and droplet transmission.

Conclusion

Rediroom is effective at containing droplets and filtering contaminated air, when fully enclosed.

rediroom

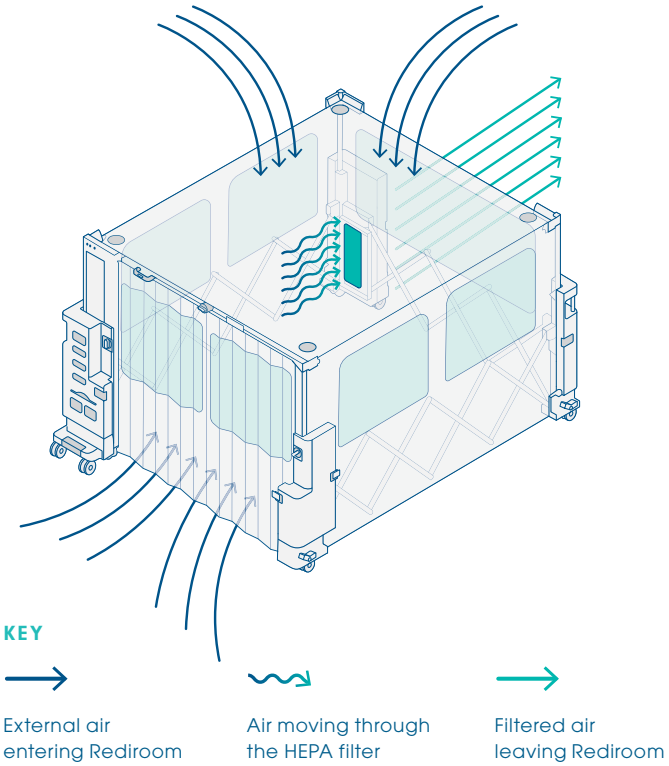
How Rediroom achieves negative airflow

Rediroom can achieve this level of containment because it generates negative airflow.

When powered on, a powerful filtration system generates 12 ACH. To achieve negative airflow, Rediroom must be correctly deployed and sealed from floor to wall – this takes only 5 minutes[5]. Rediroom is most effective when the hands-free entry/exit doors are closed.

In this state, outside air is pulled into the Rediroom through the semi-permeable ceiling and under the closed doors. Pulled across the room, air is mechanically extracted through the integrated filtration system positioned in the lower back portion of the frame.

A constant stream of air is pulled through HEPA 14 and carbon filters which trap 99.995% of particles as small as 0.3 microns. These include viruses, bacteria, respirable dust, allergens, pollen and others. The filtered air is exhausted out of the Rediroom.



Suitable for use:

- Influenza
- Diphtheria
- Mumps
- *Pertussis*
- *Meningococcus*
- Norovirus
- *Aspergillus*
- Adenovirus
- Rotavirus
- Group A *streptococcus*
- MRSA
- *C. difficile*
- Gastroenteritis of unknown aetiology
- CPE
- MDR Gram-negative organisms and other infections requiring droplet or contact precautions

Test 1: Containment of droplets

This investigation assessed the effectiveness of Rediroom to contain droplets produced by a cough simulator.

A cough simulator, based on an existing design created by Lindsley et al[6], was used to generate droplets that mimicked an infectious patient who was sat up in bed, inside a deployed Rediroom.

The droplets contained a fluorescent component, only visible with UV-A light. After simulated coughing, the room was inspected for droplet contamination and the splatter pattern mapped.

No droplets escaped Rediroom.

A host of pathogens can spread via respiratory droplets. Inside Rediroom, there is a physical barrier between infectious patients and other patients and staff. Meaning that expelled droplets cannot directly cause infection outside of Rediroom.

Inside, airborne droplets are removed by the H14 HEPA and carbon filters. The hands-free exit reduces the risk of surface contamination, and built-in PPE station puts protective equipment, hand hygiene and surface disinfectants at the point of use.

Test 2: Filtration of contaminated air

The aim of this investigation was to assess Rediroom's ability to contain and filter airborne contaminants while fully enclosed.

Smoke generators are commonly used to identify leaks in buildings and containment areas. In this case, the smoke represented airborne contaminants.

Rediroom was deployed with the doors closed, and smoke pumped in according to the defined methodology. Once filled with smoke, Rediroom was assessed for visible signs of escaping smoke.

No smoke escaped Rediroom.

When fully enclosed, Rediroom's air filtration system drives 'negative airflow'. Contaminated air exhaled by an infectious patient is mechanically extracted through the filtration system, returning filtered air to the environment, and passively bringing outside air into the room.

References

1. Mitchell BG, Williams A, Wong Z, O'Connor J. Assessing a temporary isolation room from an infection control perspective: A discussion paper. *Infect Dis Heal.* 2017;22(3):129-135
2. Health & Safety Executive. Rediroom: Visual assessment of containment of simulated human coughs. 2021.
3. Lindsley WG, Blachere FM, Thewlis RE, Vishnu A, Davis KA et al. Measurements of Airborne Influenza Virus in Aerosol Particles from Human Coughs. *PLoS ONE.* 2010;5(11):315100
4. Health & Safety Executive. Rediroom: Visual assessment of containment using a smoke generator. 2021.
5. Mitchell BG, Williams A, Wong Z. Assessing the functionality of temporary isolation rooms. *Am J Infect Control.* 2017;45(11):1231-1237
6. Lindsley WG, Reynolds JS, Szalajda JV, Noti JD & Beezhold DH. A cough simulator for the study of disease transmission by human cough-generated aerosols, aerosol science and technology. *Sci Technol.* 2013;47:8, 937-944

GAMA Healthcare Ltd.,

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The Maylands Building, Hemel Hempstead, Hertfordshire, HP2 7TG, UK.

www.gamahealthcare.com/rediroom

JBN211182

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HP2 7TG, UK.

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E info@gamahealthcare.com
gamahealthcare.com

16th September 2022

To Whom It May Concern,

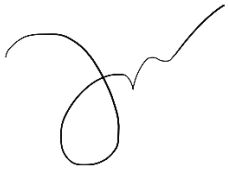
RE: Rediroom - Instant Isolation Room

Gama Healthcare Limited, a company registered In England and Wales with company number 05316871and with its registered address at The Maylands Building, Maylands Avenue, Hemel Hempstead, HP2 7TG, UK (hereinafter referred to as "GAMA") hereby confirms that It has an exclusive worldwide licence to the patent rights and know-how Incorporated in the development and manufacture of the Rediroom unit (which is a unit capable of creating an Instant, temporary, single isolation room) for the purposes of commercialising the Rediroom. An application was filed in respect of those patent rights In India (relating to the isolation method and apparatus) under reference number 814/DELNP/2015.

Rediroom provides instant patient isolation on wheels and can be deployed by a single person in under 5 minutes. Rediroom unit with capability of creating an instant, temporary, single isolation room with automatic deployment operation, inbuilt negative airflow system with minimum 12 ACH per hour, hands-free foot pedal operated entry and exit options, easily automatically deployable & foldable unit Mounted on mobile cart with lockable wheels is proprietary product exclusively manufactured by GAMA Healthcare Ltd.

It also has an exclusive licence to the Rediroom (word) trademark for the purposes of branding the Rediroom and commercialising. It on a worldwide basis. This means that GAMA has the right to use, make, have made, distribute, import, and sell the Instant Isolation room branded as Rediroom on a worldwide basis. No other company in the world is authorised to manufacture or market the same or similar product like rediroom.

Yours faithfully,



Joanne Tan
Regional Commercial Director – Asia
GAMA Healthcare Ltd.
Email: j.tan@gamahealthcare.com

Certificate of Registration
of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

GAMA Healthcare Ltd
The Maylands Building
Maylands Avenue
Hemel Hempstead Industrial Park
Hemel Hempstead, Herts, HP2 7TG
United Kingdom

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design, Manufacture and Distribution of Patient Isolation Systems and Medical Wipes and Disinfecting Sprays for Disinfecting Non-Invasive Medical Devices.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.8195)

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MD19.8195
Certification Granted: 09 January 2019
Effective Date: 24 May 2022
Expiry Date: 08 January 2025

All valid certifications are listed on NSAI's website – www.nsai.ie.
The continued validity of this certificate may be verified under "Certified Company Search"

NSAI (National Standards Authority of Ireland), 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800 E: info@nsai.ie www.nsai.ie
NSAI Inc. 20 Trafalgar Square, Suite 603, Nashua, New Hampshire, USA T +1 603 882 4412 E: info@nsaiinc.com www.nsaiinc.com

Annex to Certificate Number: MD19.8195

Scope of Registration:

The Design, Manufacture and Distribution of Patient Isolation Systems and Medical Wipes and Disinfecting Sprays for Disinfecting Non-Invasive Medical Devices.

Activity	Location
Headquarters, Administration, Manufacturing, Distribution	GAMA Healthcare Ltd The Maylands Building Maylands Avenue Hemel Hempstead Industrial Park Hemel Hempstead, Herts, HP2 7TG United Kingdom File No.: MD19.8195
Administration, Design	GAMA Healthcare Ltd Fellows Research Centre, North Dean Business Park, Stainland Road, Greetland, Halifax HX4 8LR United Kingdom File No.: MD19.8195/A

Verified by:
Director of Certification

Specifications of 4K Visualization Tower For Advance Laparoscopy Surgery

S. No	Specification
1	**Camera Processor**
	Processor for following should be quoted.: 2- Dimensional endoscopic video camera in 4K resolution (3840*2160) / 3-Dimensional endoscopic video camera in 4K resolution (3840 *2160) • System should have facility for Optical Contrast Differentiation System, and it Should have special filter for observation of capillary vessels and fine patterns in the superficial layer of mucosa for early detection of lesions. • System Should be capable of Near Infrared fluorescence Imaging (ICG application) with below features: a) Overlay: White light image with superimposed display of NIR/ICG fluorescence. Possible to select the preferred color for NIR/ICG imaging: Either blue or green. b) Monochromatic: NIR/ICG fluorescence signal in white. Background in black for maximum contrast. c) Intensity Map: White light image with superimposed display of NIR/ICG fluorescence. NIR/ICG signal display will appear in different colors depending on the strength of the detected NIR signal. • Picture in Picture of visualization modes with Standard and Optical Contrast Differentiation. • Automatic adjustment of light intensity of light source and controlled from Camera head. • Outputs: All Compatible outputs should be there (12GSDI, D.P) for 4K resolution and DVI for HD resolution.
2	**4K Camera Head**
	Technical Specifications: Pixels 3840 X 2160 Pixels AGC: Microprocessor controlled Lens: Integrated Zoom Lens f = 19 mm Color Space BT.2020 emulation Control buttons: 3 (2 of them freely programmable). • **Camera Head Should be able to perform both White light and Near Infrared application.**
3	**32 Inch or more Monitor – QTY 1 each**
	ALL in one Medical Grade Monitor capable of displaying: • 3D in 4K resolution / 2D in 4K resolution • 2D in Full HD resolution / 3D in Full HD resolution Certified to: ANSI/AAMI ES60601-1:2005, UL 60601-1, CAN/CSA C22.2 NO.60601-1:14 und EN 60601-1. CE label according to MDD, class I.
4	**LED Light source with Fiber optic cable**
	• Should have Lumen >2000 • Lamp life of approx. 30,000 hrs. • 4.8mm Fiber Optic Cable and 300cm Long

	• Should have touch display which provides an intuitive & user-friendly interface that directly displays relevant data • Lamp type: High-performance LEDs, white light LED and near infrared LED, which are active individually or simultaneously. Certified To: - IEC 601-1 & UL 544 CE According to MDD, protection class 1/CF
3	**TELESCOPES for 2D**

LAPAROSCOPY STAPLERS

Sr. No.	Description
4	Laparoscopic staplers and reloads 60mm Green and Blue with close staple height of 2.0 mm and 1.5 MM

Essential Criteria:

1. First 5 years equipment will be under warranty which will be covered with the cost of the equipment

2. Demonstration mandatory at hospital premises at OEM cost.

3. Training of 5 Doctors to be arranged at a center of international repute.

4. CMC offered for quoted equipment should not be more than 5% of the quoted model with not more than 5% escalation per year after completion of warranty period- 6^{th} to 10^{th} year.

5. CMC offered for the quoted equipment must be on OEM letterhead. (CMC offered on distributors/Vendor letterhead will not be considered).

6. Installation process should be performed by OEM trained service engineer/ service representative on OEM's letter head/ service report, with a mandatory provision of providing preventive service visit of OEM trained service engineer/service representative quarterly per year till completion of warranty period (i.e. 20 visit for first five years) and further quarterly visit (04 visits/ year) till the completion of CMC period.

7. The installation process must be completed by the OEM/Service provider within 30 days of supply.

8. In case of technical snag/ failure/breakdown, the response time for inspection should be within 24 hours and repair with 5 days, otherwise provide a service machine until the period of recovery of breakdown of the unit. Failing which will attract penal action as per the decision of the GSVM Medical College (Uptime guarantee of 95%).

9. All the technical specifications accepted in the compliance statement must be supported by Original Literature from the firm/O.E.M with Highlighting, Numbering and flagging it's per below mentioned format for the compliance statement

S. NO	Technical Specification	Compliance Yes/NO	Page No. in the proposal submitted where documentary evidence is enclosed as per tender Specs with highlighting Numbering & flagging

UnivLabs
Care for ALL

MANUFACTURERS' AUTHORIZATION FORM

To,
The Principal And Dean
Ganesh Shankar Vidyarthi Memorial Medical College ,
Swaroop Nagar Kanpur U.P ,India

Dear Sir:

We UnivLabs Technologies Pvt Ltd who are established and reputable manufacturers Laparoscopic set having factories at Plot No. 31, Lower Ground Floor, Near Infocity II, Sector 33, Gurugram-122003 (HR) ,www.univIabs.in*)* do hereby authorize **M/S Oriental Surgical Works 1708/ 09 Mittal Market Bhagirath Place Chandni Chowk Delhi** for Bidding

No company or firm or individual other than **M/S Oriental Surgical Works 1708/ 09 Mittal Market Bhagirath Place Chandni Chowk Delhim/S Oriental Surgical Works 1708/ 09 Mittal Market Bhagirath Place Chandni Chowk Delhi** for Bidding

Thanks & Regards,

Univlabs Technologies Private Limited

Director

Sunil Singh, Founder CEO

.

Note: This letter of authority should be on the letterhead of the manufacturer and should be signed by a person competent and having the power of attorney to legally bind the manufacturer. It should be included by the Tenderer in its tender.

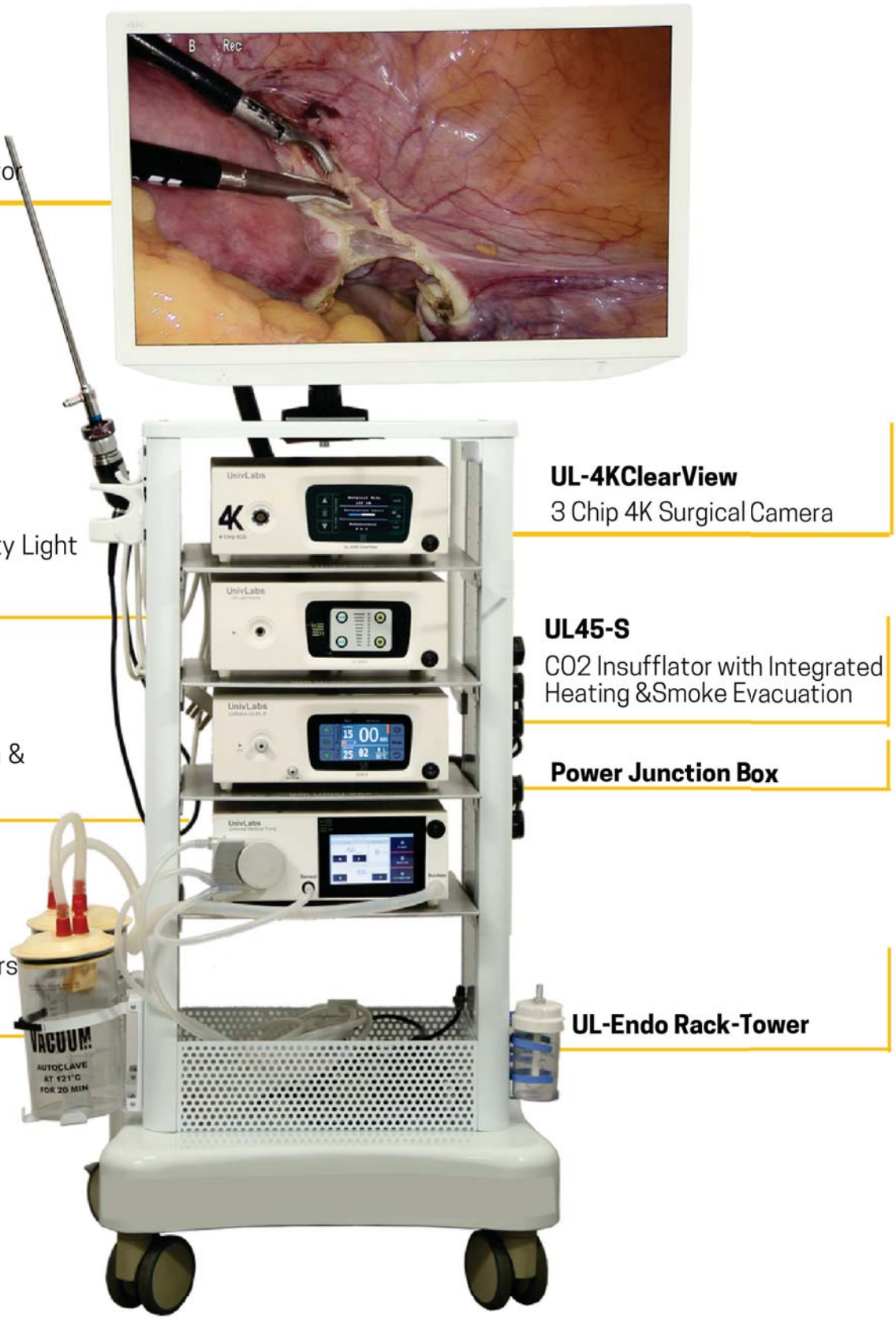
UNIVLABS

4K LAPAROSCOPY SURGERY SYSTEM

UL-UHD ClearView

UL-UHD CLEARVIEW
4K 3 CHIP CMOS TECHNOLOGY
UNPARALLELED VISUAL EXPERIENCE

UnivLabs
Care for all



ULSM-32-4K
4K Surgical Monitor

UL-9000
Smart Body Cavity Light Source

UMP-1000
Universal Irrigation & Suction Pump

UL-JD2L
Fluid Collection Jars with Auto Lock

UL-4KClearView
3 Chip 4K Surgical Camera

UL45-S
CO2 Insufflator with Integrated Heating &Smoke Evacuation

Power Junction Box

UL-Endo Rack-Tower

SURGICAL MEDICAL GRADE MONITOR

UL-SM32-4K

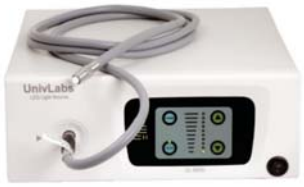
- Designed specifically for the surgical environment, the **UL-SM32-4K UHD** monitor meticulously renders highly detailed and sharp imagery, replicating a lifelike portrayal of the surgical field. The 4K IPS display provides visual comfort for viewing accurate images from any angle, which reduces the risk of misperception and helps to produce better outcomes. Enhanced color accuracy and depth perception enable surgeons to access realistic, detailed images
- 32" **4K** (3840 x 2160) IPS Display | Brightness Stabilization | Supports HDR10 Viewing Angle 178 Degree | Mirror & Rotate mode | Dustproof & Water-Resistant Protection glass for disinfection | DICOM-14 compliant

3 CHIP 4K ULTRA HIGH DEFINITION CAMERA

- Introducing the **UL-3CHIP-4K** Ultra High-Definition Camera System, designed to deliver unparalleled surgical visualization. With advanced 3-Chip CMOS technology and premium optics, it captures surgical details in stunning 4K clarity. To streamline setup, we offer five pre-configured surgical specialty settings, saving time and ensuring precision. It elevates surgical procedures with lifelike imagery, empowering surgeons to perform with confidence.
- 3 x 1/3" CMOS (3840 x 2160) Pixel (UHD) 60fps | Optical & Digital Zoom Function Selectable 4K & HD Output | Color Enhancement & Saturation for better surgical outcome | Zoom, Freeze and Smoke Reduction | Five user modes | Camera head with 3 easy-to-use buttons for seamless control | HD SDI & HDMI Output

UL-3CHIP-4K

SURGICAL LED LIGHT SOURCE



UL-9000

- Revolutionizing the operating room, our innovative LED technology transforms the way light sources are utilized. This device incorporates a safety feature that automatically disables the light source when it reaches an unsafe temperature, mitigating the risk of patient skin burns. With LED bulbs boasting an impressive lifespan of 50,000 hours, not only is this solution environmentally friendly, but it also dramatically reduces operational costs.
- PWM Control | User-friendly on-screen control interface for light intensity | Auto Switch-off to prevent burns | Membrane Touch; 10-step dimming for quick intensity control Rendering colors with a high degree of accuracy with 90 CRI | Color temperature: 6500K | Self Heat Regulation | Saves last used configuration

UNIVERSAL MEDICAL IRRIGATION PUMP

- The **UMP-1000** is our cutting-edge innovation in delivering secure, seamless, dependable, and uniform performance in medical procedures for irrigation, suction, and intra-cavitary distension. Self-test automatically at on power at 100mmHg, 200mmHg, 300mmHg, 400mmHg | Irrigation Flow range 100-1000 ML/Min | Pressure Range 50-400 mmHg Powerful Suction at 0.65 bar |
- Intracavity Pressure Display | Flushing Function | Dual MEMS
  Reusable Medical-Grade Silicon
  -Irrigation Tubing - 05 MM (ID) x 09 MM (OD)
- -Suction Tubing Dimension- 10 MM (ID) x 16 MM (OD)

UMP-1000

ENDOSCOPES

UnivLabs **Ultra HD Telescopes**, where excellence in optical engineering meets unparalleled performance. Our telescopes boast top-tier quality optics that deliver remarkable contrast and impeccable color accuracy. With cutting-edge high-performance lenses, these telescopes offer a full HD image experience that maintains exceptional contrast, optimal light transmission, and remarkable depth of field.

Key Features:

- Homogenous and sharp-edged illumination
- Optimized optical system for very bright images with rich contrast
- Gold soldering of the plan glass increases tightness and durability
- Sealed tight laser-welded outer tube protects the system, resulting in long life cycles for the optical components

CO2 INSUFFLATOR

UL45-S

Introducing the UL45-S, an advanced CO2 Insufflator engineered for exceptional performance in medical settings. With a strong focus on safety and user convenience, this device ensures rapid pneumoperitoneum creation without compromising patient well-being.

Swift Pneumoperitoneum Creation: The UL45-S enables the rapid establishment of a pneumoperitoneum, allowing surgeons to commence procedures promptly and reduce anesthesia time.

Unrivaled Safety: This device places safety at the forefront, minimizing risks and enhancing patient outcomes.

Innovative Safe VENT® & DualDome Technology: Benefit from cutting-edge technology that guarantees optimal pneumoperitoneum while maintaining unparalleled safety standards.

Integrated Smoke Evacuation System: Designed to effectively eliminate surgical smoke generated during cauterization procedures, the UL45-S ensures uninterrupted visual clarity for surgical precision. Experience the difference with the UL45-S, where safety, speed, and clarity converge for superior laparoscopic surgeries.

Key Features:

Flow up to 45 Litres per minute | Pressure Range- 0-30 mmHg | Dedicated options for Veress, Paediatric & Normal modes | Dual CO2 input feature (for CO2 Central Line & High-Pressure Cylinder) | Two Stage Gas heating system | Redundant MEMS Pressure Sensor | VoiceCoil Precision Flow Control

Alarms: Open flow warning | Dangerous Pressure rise warning | Tube occlusion warning | Pressure sensor error warning

DOCUMENTATION SYSTEM

UL-REC-HD

In-built screen ,Support HDMI/SDI/RS232/VGA

Record-able Storage: USB Flash Drive, USB Hard Drive, 2.5 inch Hard Drive. (Supports FAT, FAT32 and NTFS format)

Display: 4.3 inch TFT | Power Supply: DC 12V3A | Operating temperature: 41 to 104 deg F (5 to 40 deg C)

Storage temperature: -4 to 140 deg F (-20 to 60 deg C) | Operating humidity: 5% to 80% Dimensions / Weight: 262(L) X 172(W) X 120(H) mm / 1.6Kg

CERTIFIED ISO 9001:2015 COMPANY

BN 19793/18901

BSCIC

MEDICAL DEVICES ISO ISO 13485:2016 QUALITY MANAGEMENT

BN 19580/18902

UnivLabs
Care for all

Your Reference No

Date:- 22.07.2024

Our Reference:-

PROPRIETARY ARTICLE CERTIFICATE

This certifies that the 4K High-Resolution Laparoscopic Surgery System (UL-UHD-Clearview), which includes the Camera Control Unit, Camera Head, Coupler, LED Light Source, CO_2 Insufflator, Suction and Irrigation Pump, 10mm 0 and 30-degree Telescope, and 5mm 0 and 30-degree Telescope, are proprietary products of UnivLabs Technologies Pvt. Ltd.

With Best Regards,
Univlabs Technologies Private Limited
For Univlabs Technologies Pvt Ltd

Director

Sunil Kumar Singh

CERTIFICATE ▪ CERTIFICATO ▪ ZERTIFIKAT ▪ SERTİFİKA ▪ CERTIFICADO ▪ گواهینامه ▪ ΠΙΣΤΟΠΟΙΗΤΙΚΟ ▪ شهادة ▪ 证明 ▪ 証明書 ▪ 인증서

CERTIFICATE

CERTIFICATE No. MTIC/MD/1129

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

UnivLabs Technologies Private Limited

Plot 31, Sector-33, Near Infocity-II, Gurugram Haryana India-122 003

IS IN COMPLIANCE WITH THE REQUIREMENTS OF STANDARD

ISO 13485:2016

THIS CERTIFICATE IS VALID FOR THE FOLLOWING ACTIVITIES

Design and Development, Manufacture, Sales, Supply and Service of Endoscopy Tower system and Accessories.

Permissible Exclusion: 7.5.5 Particular requirements for sterile medical devices 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems 7.5.9.2 Traceability – Particular Requirements for Implantable Medical Devices

AUDIT REPORT No. MTIC/MED/0362

First issue date 25-06-2024 Revision date: 25-06-2024 Expiry date 24-06-2027

The validity of this certificate is subject to periodical audits and the complete re-assessment of the system every three years. For any further question with regard to this certificate please contact www.mtic-group.in

QM-028

Place : Bengaluru

Head of Certification

MTIC INTERCERT Certification Body

MTIC InterCert India Private Limited
No. 122/1, 3rd Main Road, Margosa Road, Malleswaram, Bengaluru - 560 003, Karnataka, India
www.mtic-group.in india@mtic-group.in

CERTIFICATE ▪ CERTIFICATO ▪ ZERTIFIKAT ▪ SERTİFİKA ▪ CERTIFICADO ▪ گواهینامه ▪ ΠΙΣΤΟΠΟΙΗΤΙΚ

फार्म III {स्कीम–III के पैरा 3 के उप–पैरा (5) को देखें}
Form III {Refer Sub-Para (5) of Para 3 of Scheme III}

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
चिकित्सा उपकरण पद्धति प्रमाणन लाइसेंस
LICENCE FOR THE MEDICAL DEVICES MANAGEMENT SYSTEMS

अनुज्ञप्ति सं / Licence No./NR/ MDMS/ L - **9000027**

ब्यूरो, भारतीय मानक ब्यूरो अधिनियम, 2016 (2016 का 11) प्रदत्त शक्तियों के नाते पर निम्नलिखित को मंजूर करता है:

By virtue of the power conferred on it by the Bureau of Indian Standards Act 2016 (11 of 2016), the Bureau hereby grants to: -

मै. यूनीवलैब्स टेक्नोलॉजीज प्राइवेट लिमिटेड,
प्लॉट 31, निचला भूतल,
इन्फोसिटी II के पास, सेक्टर 33,
गुरूग्राम-122003, हरियाणा, भारत

M/s Univlabs Technologies Private Limited,
Plot 31, Lower Ground Floor,
Near Infocity II, Sector 33,
Gurugram-122003, Haryana, India

को (जिसे इसमें इसके पश्चात इसे अनुज्ञप्तिधारी कहा गया है) इस अनुसूची में वर्णित विशेष तौर पर उत्पाद एवं/ या सेवाओं की प्रक्रियाओं के संबंध में ब्यूरो के चिकित्सा उपकरण प्रबंध प्रणाली प्रमाणन के अनुज्ञप्तिधारकों की ब्यूरो की सूची में इस अनुज्ञप्ति के अनुसार इसी संख्याधारक को अधिकार एवं अनुज्ञप्ति सूचीबद्ध किया जाए । आई एस/आई एस ओ **13485:2016** के अनुसार चिकित्सा उपकरण प्रबंध प्रणाली के अधीन उक्त दिए गए पते (पतों) पर केवल अनुज्ञप्तिधारक द्वारा ऐसे उत्पाद एवं/ सेवाओं या प्रक्रियाओं को निर्मित किया/ उपलब्ध कराया/ चलाया जायेगा।

(hereinafter called the Licensee) the right and licence to be listed in the Bureau's List (s) of Licensees of Medical Device Management Systems Certification in respect of the products and/or services of process particularly described in the schedule hereto, bearing the same number as this licence. Such products and/or services or processes shall be manufactured/ provided/carried out by the Licensee at only the address(es) given above, and under the Medical Device Management Systems in accordance with **IS/ISO 13485:2016.**

अनुज्ञप्ति उक्त अधिनियम एवं उनके अधीन नियमों तथा विनियमो के संबंधित उपबंधों की शर्त पर मंजूर किया गया है तथा उक्त संदर्भित अनुज्ञप्तियों को इसके तहत शासित किया जाता है, तथा अनुज्ञप्तिधारक उक्त नियमों एवं विनियमों का पालन किए जाने के लिए ब्यूरों के प्रति प्रतिज्ञाबद्ध है ।

The licence is granted subject to the relevant provisions of the above Act and the Rules and Regulations made thereunder governing the licences referred to above, and the Licensee hereby covenants with the Bureau duly to observe with the said Rules and Regulations.

यह अनुज्ञप्ति 22/02/2024 से तारीख 13/09/2026 तक विधिमान्य रहेगा तथा विनियमो में यथा रहित पुन: प्रमाणन दिया जा सकेगा।

This licence shall be valid from 22/02/2024 to 13/09/2026 and may be recertified as prescribed in Regulations.

यह तारीख **फ़रवरी 2024** 22nd दिन को हस्ताक्षरित एवं मुहरांकित तथा दिनांकित किया गया ।
Signed, Sealed and Dated this **day of February 2024**.

Note: This licence has been granted under Transfer of Licence Guidelines MSC-G6.6-04, Issue No. 03, Oct 2023.

(Rajeev P.)
उप महानिदेशक (उत्तर)
कृते भारतीय मानक ब्यूरो
Deputy Director General (North)
for BUREAU OF INDIAN STANDARDS

भारतीय मानक ब्यूरो IS/ ISO 13485
BUREAU OF INDIAN STANDARDS MDMS

मानक: पथप्रदर्शक:

M D M S

अनुज्ञप्ति सं /एन आर/ एमडीएमएस/ एल - 9000027 की अनूसूची

Schedule to Licence No./NR/MDMS/ L –9000027

मै यूनीवलैब्स टेक्नोलॉजीज प्राइवेट लिमिटेड प्लॉट 31, निचला भूतल, इन्फोसिटी II के पास, सेक्टर 33, गुरूग्राम-122003, हरियाणा, भारत को जारी किया गया

Issued to M/s Univlabs Technologies Private Limited, Plot 31, Lower Ground Floor, Near Infocity II, Sector 33, Gurugram-122003, Haryana, India

अनुसूची
SCHEDULE

वे उत्पाद/ सेवा/प्रक्रिया जिसके लिए फर्म को चिकित्सा उपकरण प्रबंध पद्धति प्रमाणन हेतु अनुज्ञप्ति को पुन: प्रमाणित किया गया है।

Products/Services/Processes with respect to which the licence of the firm has been granted for its Medical Device Management Systems Certification:

"Design & Development, Manufacture, Sales, Supply and Service of Endoscopy Tower System & Accessories," with Particular Requirement for Sterile Medical Devices (clause 7.5.5), Particular Requirement for Validation of Sterilization and Sterile Barrier Systems (clause 7.5.7), Particular Requirement for Implantable Medical Devices (clause 7.5.9.2), as not applicable.

22/2/2024

(Rajeev P.)
उप महानिदेशक (उत्तर)
कृते भारतीय मानक ब्यूरो
Deputy Director General (North)
for BUREAU OF INDIAN STANDARDS

भारतीय मानक ब्यूरो IS/ ISO 13485
BUREAU OF INDIAN STANDARDS MDMS

Food and Drugs Administration Haryana
SCO-94, SEC-5, Panchkula

From

State Drugs Controller-cum-Licensing Authority
Food and Drugs Administration, Haryana,
SCO-94, Sector-5, Panchkula.

To

M/s UnivLabs Technologies Private Limited,
Plot No 31, Near Infocity II, Sector 33, Gurgaon,
Haryana (India) – 122003

Dated : 22.02.2024

Subject: **Regarding grant of license to manufacture for sale or for distribution of class A or Class B medical device.**

With reference to your application no. MFG/MD/2023/94720 dated 12.06.2023 on the subject cited above.

Find enclosed herewith copy of Form MD-5 having Medical Devices (Class A & B) manufacturing license no. MFG/MD/2024/000102 w.e.f. 22.02.2024 to 21.02.2029.

Digitally signed by Manmohan Taneja
Date: 2024.02.22 16:18:48

State Drugs Controller Haryana

सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2024/000102

1. M/s UNIVLABS TECHNOLOGIES PVT. LTD., Regus Office Center Gurgaon Pvt Ltd, Level 9, Spaze I-Tech,A-1 Tower, Sector 49, Sohna RoadGurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 9560925518 FAX: 9560925518 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s UnivLabs Technologies Private Limited, Plot No 31/sf, Near Infocity II, Sector 33, Gurgaon, Haryana (India) - 122003 Telephone No.: 9560925518 FAX: 9560925518

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Hysteroscopic insufflator Model No.:Uniflator - UL45 - S - Two step temp. control to avoid Hypothermia. Dual Mechanical Safety Valve. Dual Electric Safety System High pressure Vent, Safe VENT, Gas Flow rate: 2 to45 L/min,Uniflator (UL45-D) - Two step temp. control to avoid Hypothermia. Dual Mechanical Safety Valve. High pressure Vent, Safe VENT®.,Uniflator (UL-SE16) - Laparoscopy Smoke Evacuator Safe-Air smoke evacuator for clear vision, UnivLabs UL - Dual Dome technology with coil-based flow control Intended Use:A device that sends the gas into the fallopian tube to maintain the patency of the tubes. Class of medical device:Class B Material of construction:Brass, Stainless steel, Silicon, GPSP, Polypropylene, Al-6064, teflon (PTFE), Soft iron, Rubber Dimension(if any):360 x 310 x 130 mm Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):UnivLabs Laparoscopy Uniflator

2	Generic Name:Powered suction pump Model No.:UMP-1000 - - Intra cavity pressure management, piezo pressure sensor, disposable tubing, freeze flow, 0.01-1.0 l/min. Suction and flow change options, Membrane touch screen, HY-1000 - - Intra cavity pressure management, piezo pressure sensor, disposable tubing, freeze flow, 0.01-1.0 l/min. flow change options, Membrane touch screen, Irrigation Purpose,, Lap M-1000 - Fix flow capacity, Membrane touch,GFM-1000 - Gastro Pump with light source and suction ,UMP-2000 - Intra cavity pressure management, piezo pressure sensor, disposable tubing, freeze flow, 0.01-2.0 l/min. Suction and flow change options, Membrane touch screen. Intended Use:A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter Class of medical device:Class B Material of construction:Aluminium, Delrin, SS, ABS, Plastic, GP Sheet, Poly urethane Dimension(if any):310 x 120 x 330 mm Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):UnivLabs Suction Irrigation Pump

Digitally signed by Manmohan Taneja
Date: 2024.02.22 16:19:42

Place:

Date22-Feb-24

State Licensing Authority

Online System for Medical Devices

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S.No	File No	Devices (Brand Name)	Certificates
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