

# **Manufacturer's Certification**

**Gel Craft Healthcare (P) Limited**

**WHO-GMP**

# Certificate of Compliance



**This is to certify that**  
Good Manufacturing System

of

**GEL CRAFT HEALTHCARE PVT.LTD**

at

**A2/48, SITE-IV, SAHIBABAD INDUSTRIAL AREA GHAZIABAD,  
UTTAR PRADESH – 201010**

**has been independently assessed and is  
compliant with the requirements of:**

**WHO-GMP**

**For the following scope of activities:**

C31 GEL® (MEDIGEL®) TECHNOLOGY BASED FOOTCARE PRODUCTS, HEALTHCARE PRODUCTS, CUSHIONING / BED SORE PREVENTION PRODUCTS, OPERATION THEATRE POSITIONING DEVICES, FOOTWEAR AND SPORTS PRODUCTS, DRDO TECHNOLOGY VISCOELASTIC GEL WITH ANTI-MICROBIAL COVID COAT, DRDO CBRN ULTRA DEVICES, ULTRA SWACHH PPE DISINFECTION UNIT, ATI SWACHH – HEAT SENSITIVE MEDICAL DEVICE DISINFECTION UNIT, OZONATED RADICAL CONFINED SPACE DISINFECTION UNIT (POORAN SWACHH), TRI-NETRA HAND SANITIZATION UNIT, TAARAN PATIENT TRANSFER SYSTEM, SAMGRAH SWACHH, VAYU SWACHH, VISANKRA OT STERILIZATION UNIT, TRIYOGANI HAND SANITIZER, TRIYOGANI FUMIGATION, COVID COAT PLUS

**This certificate is issued under the following conditions:**

- It applies only to the quality system maintained in the manufacture of above referenced scope / activities.
- The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the WHO-GMP Guidelines
- The certificate validity is conditioned by positive results or surveillance audits

**Certificate Number: UQ-901241**

Validity of this certificate can be verified at [www.ukglobals.uk/Verify](http://www.ukglobals.uk/Verify)

Date of Certification

09 March. 2021

1<sup>st</sup> Surveillance Audit

08 March. 2022

2<sup>nd</sup> Surveillance Audit

08 March. 2023

Certificate Expiry (subject to the company maintaining its system to the required standard)

08 March. 2024

414

**Authorised Signatory**



This certificate is the property of UK Global Certification & Inspection Limited and shall be returned immediately on request.

71-75 Shelton Street Covent Garden London United Kingdom WC2H 9JQ

Website:- [www.ukglobals.uk](http://www.ukglobals.uk), [enquiries@ukglobals.uk](mailto:enquiries@ukglobals.uk)

Company No. 11847851

Uk Global Certification & Inspection Limited

**ISO**

**13485: 2016**

شهادة



ZERTIFIKAT



CERTIFICATO



CERTIFICADO



CERTIFICATE



**MASMELLO**  
Certification Pvt Ltd



*Certificate of Compliance*

This is to certify that the

Medical Device Quality Management System

of

**GEL CRAFT HEALTHCARE PVT.LTD**

at

A2/48, SITE-IV, SAHIBABAD INDUSTRIAL AREA GHAZIABAD,  
UTTAR PRADESH – 201010

has been independently assessed and is  
compliant with the requirements of:

**ISO 13485:2016**

For the following scope of activities:

C3I GEL® (MEDIGEL®) TECHNOLOGY BASED FOOTCARE PRODUCTS, HEALTHCARE PRODUCTS, CUSHIONING / BED SORE PREVENTION PRODUCTS, OPERATION THEATRE POSITIONING DEVICES, FOOTWEAR AND SPORTS PRODUCTS, DRDO TECHNOLOGY VISCOELASTIC GEL WITH ANTI-MICROBIAL COVID COAT, DRDO CBRN ULTRA DEVICES, ULTRA SWACHH PPE DISINFECTION UNIT, ATI SWACHH – HEAT SENSITIVE MEDICAL DEVICE DISINFECTION UNIT, OZONATED RADICAL CONFINED SPACE DISINFECTION UNIT( POORAN SWACHH), TRI-NETRA HAND SANITIZATION UNIT, TAARAN PATIENT TRANSFER SYSTEM, SAMGRAH SWACHH, VAYU SWACHH, VISANKRA OT STERILIZATION UNIT, TRIYOGANI HAND SANITIZER, TRIYOGANI FUMIGATION, COVID COAT PLUS

Certificate Number: MD-9014121

This certificate is issued under the following conditions:

1. Fulfilled are requirement as per implemented of suggested standards
2. The certificate remains valid until the manufacturing conditions are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant Standard testing performance, the manufacturer shall affix to each device, of the referenced models.

The compliance as shown above can be used, under the responsibility of the manufacturer, after completion of a Declaration of conformity an compliance with all relevant Standard requirements. The statement is based on a single evaluation of one sample of above-mentioned product It does not imply an assessment of the whole production.

Validity of this certificate can be verified at [www.mplcert.com/Verify](http://www.mplcert.com/Verify)

Date of Certification	09 April. 2021
1 <sup>st</sup> Surveillance Audit Due	08 April. 2022
2 <sup>nd</sup> Surveillance Audit Due	08 April. 2023
Certificate Expiry (subject to the company maintaining its )	08 April. 2024

Authorised Signatory



The Registration is a Quality Certificate, \*Subject to successful completion of surveillance audits, visit for verification on "Certificate is the property of MPL and return when demanded".

MPL certification is accredited by International Certification and inspection UK Limited (ICIL)  
71-75 Shelton Street, Covent Garden, London, United Kingdom, WC2H 9JQ  
India Office: Masmello certification Private Limited A-72 Ground Floor Swarn Park Mundka Delhi-110041  
mplcert@gmail.com, Info@mplcert.com, website: mplcert.com  
Company Number 353042

# **Certificate of Recognition**

**[StartUp India]**

CERTIFICATE NO:  
DIPP80455



सत्यमेव जयते

Government of India  
Ministry of Commerce & Industry  
Department for Promotion of Industry and Internal Trade

#startupindia

# CERTIFICATE OF RECOGNITION

*This is to certify that **GEL CRAFT HEALTHCARE PRIVATE LIMITED** incorporated as a **Private Limited Company** on **19-08-2014**, is recognized as a startup by the Department for Promotion of Industry and Internal Trade. The startup is working in 'Healthcare & Lifesciences' Industry and 'Medical Devices Biomedical' sector as self-certified by them.*

**This certificate shall only be valid for the Entity up to **Ten** years from the date of its incorporation only if its turnover for any of the financial years has not extended ₹ 100 Cr.**

25-05-2021

DATE OF ISSUE

18-08-2024

VALID UPTO

# **ISO 9001: 2015**





# Certificate of Registration

This is to certify that

**GEL CRAFT HEALTHCARE PVT. LTD.**

A2/48, SITE-IV, SAHIBABAD INDUSTRIAL AREA, GHAZIABAD – 201010,  
UTTAR PRADESH, INDIA

has been independently assessed by QRO  
and is compliant with the requirement of:

**ISO 9001:2015**

**Quality Management System**

For the following scope of activities:

Providing C3I Gel ® ( Medigel ®) Technology Based Footcare Products, Healthcare Products, Cushioning / Bed Sore Prevention Products, Operation Theatre Positioning Devices, Footwear and sports Products, DRDO Technology Viscoelastic Gel with Anti-Microbial Covid Coat , DRDO CBRN Ultra Devices, Ultra Swachh PPE Disinfection Unit, Ati Swachh – Heat Sensitive Medical Device Disinfection Unit, Ozonated Radical Confined Space Disinfection Unit( Pooran Swachh), Tri-netra Hand Sanitization Unit, Taaran Patient Transfer System, Samgrah Swachh, Vayu Swachh, Visankra OT Sterilization Unit, Triyogani Hand Sanitizer, Triyogani Fumigation, Covid Coat Plus

Date of Certification: 10th April 2021

1<sup>st</sup> Surveillance Audit Due: 9th April 2022

2<sup>nd</sup> Surveillance Audit Due: 9th April 2023

Certificate Expiry: 9th April 2024

**Certificate Number: 305021041024Q**



*Chaman ..*  
Head of Certification

Validity of this certificate is subject to annual surveillance audits to be done successfully on or before 365 days from date of the audit.  
(In case if surveillance audit is not allowed to be conducted: this certificate shall be suspended / withdrawn).

The Validity of this certificate can be verified at [www.qrocert.org](http://www.qrocert.org)

This certificate of registration remains the property of QRO Certification LLP, and shall be returned immediately upon request.

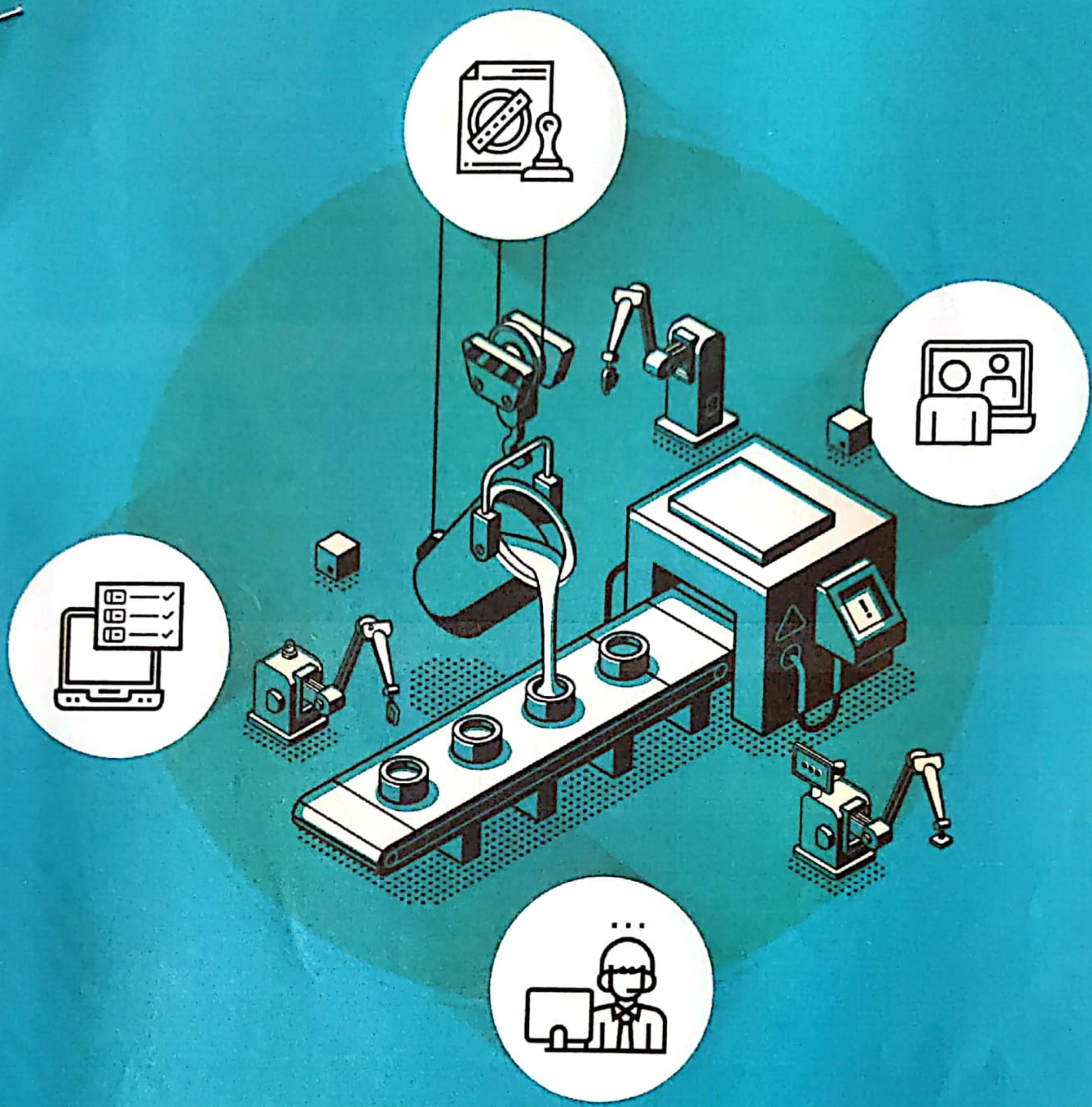
India Office : QRO Certification LLP

142, 11nd Floor, Avtar Enclave, Near Paschim Vihar West Metro Station, Delhi-110063, (INDIA)

Website : [www.qrocert.org](http://www.qrocert.org), E-mail : [info@qrocert.org](mailto:info@qrocert.org)

# **Quality Control of India (QCI)**

**Govt e-Marketing (GeM) Portal  
Government of India (GoI)**



# VENDOR ASSESSMENT REPORT

September 25<sup>th</sup>, 2019

GEL CRAFT HEALTHCARE PRIVATE LIMITED

VA-452406780849961



# **Technology Transfer (Ultraswachh)**

# Technology Transfer Document

## Ultra Swachh

Personal Protective Equipment Disinfection Unit (Tri-Netra):  
Multi-Product

U<sub>s</sub> Technology

**Developed by**

**Team, Division of CBRN Defence**

August, 2020'

First Prototype Delivery: May' 2020'

First Product Launched by DRDO: June, 2020'

Multi-Product (U<sub>s</sub>) Series Delivery : October, 2020'



## Institute of Nuclear Medicine and Allied Sciences

Brig SK Mazumdar Marg, Delhi-110054, India

<p>Date..... 20/10/2020 Signature..... Director Lab/Bstn Tech Coord &amp; Pkg. Div.</p>	<p>For Gel Craft Healthcare Pvt. Ltd.</p> <p>(Authorised Signatory) M/s Gel Craft Healthcare (P) Limited</p>
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