SGS

TEST REPORT

Report No. : CH:TX:1142028342 **DATE : 29/09/2020**

GEL CRAFT HEALTHCARE PRIVATE LIMITED
A-2/48, SITE-IV SAHIBABAD INDUSTRIAL AREA
GHAZIABAD-201010
IN
CONTACT PERSON : MR. AJAY GUPTA

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION	AUXILARIES MEDICAL GRADE GEL - OT POSITIONING PAD
COLOUR	TRANSPARENT
END USE	OPREATION THEATER POSITIONING PAD
REFERENCE NO.	GC/2020/REACH/01
BUYING HOUSE	**NOT PROVIDED**
COUNTRY OF DESTINATION	INDIA
COUNTRY OF ORIGIN	INDIA
SAMPLE RECD ON	10/09/2020 **TESTING PERIOD :** 19/09/2020 - 29/09/2020

As requested by client, SVHC screening is performed according to:

- Two hundred and nine (209) substances in the Candidate List of Substances of Very High Concern (SVHC) for authorization published by European Chemicals Agency (ECHA) on June 25, 2020 regarding Regulation (EC) No 1907/2006 concerning the REACH

Test Result(s) : Please refer to next page(s).

Summary:

According to the specified scope and analytical techniques, concentrations of tested SVHC are ≤ 0.1% (w/w) in the submitted sample. Concentrations of tested SVHC with specific concentration limit (SCL) # < 0.1% (w/w) set in Regulation (EC) No. 1272/2008 and its amendments are < reporting limit.	PASS

Per pro SGS India Private Ltd

P.SHANMUGAM
EXECUTIVE
Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

JOE No. : 2042815203 4616618 Page 1 of 10 Control No.:1142533128

SGS India Private Ltd. | Consumer and Retail, Testing Laboratory, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai - 600 058. India.
t : (91-44) 6608 1600. www.sgs.com
Member of the SGS Group (SGS SA)

INMAS Delhi/डी.आर.डी.ओ. Date: 20/10/2020 Signature..... Director Lab/Estt. Tech Coord & PM DIV.

For Gel Craft Healthcare Pvt. Ltd.
(Authorised Signatory) Director
M/s Gel Craft Heathcare (P) Limited

License No. DRDO/DI²TM/2020/1135

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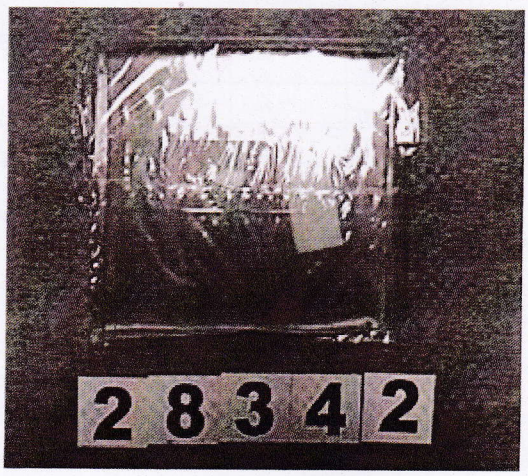
Sample photo:



SGS authenticate the photo on original report only

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इनमास दिल्ली/INMAS Delhi/डी.आर.डी.ओ./DRDO
Date: 29/10/2020
Signature
Director Lab/Estt
Tech Coord & PM Div.

For Gel Craft Healthcare Pvt. Ltd.

(Authorised Signatory)
M/s Gel Craft Heathcare (P) Limited

License No. DRDO/DI²TM/2020/1135

Certificate of Compliance

We Hereby Declare That the Technical File of Product Complied with The Requirement of Machine Directive 2006/42/CE

Certificate No.: CE-97801

COMPANY NAME :- **GEL CRAFT HEALTHCARE PVT.LTD**

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

PRODUCTS :- **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 , ULTRA SWACHH – PERSINAL PROTECTIVE EQUIPMENT DISINFECTION UNIT , TRI-NETRA HAND SANITIZATION UNIT, TAARAN (SAFE PASSAGE) PATIENT TRANSFER SYSTEM , ORCS SANITIZATION UNIT (POORN SWACHH) , ATI SWACHH HEAT SENSITIVE MEDICAL DEVICE DISINFECTION UNIT , TRIYOGANI HAND SANITIZATION SOLUTION , TRIYOGANI FUMIGATION SOLUTION , COVID COAT 90 DAYS DISINFECTION SOLUTION , SAMAGRAH SWACHH FRUIT & VEGETABLE WASH & OZONATED SPACE STERILIZERS**

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Machine Directive 2006/42/CE

This certificate is issued under the following conditions:

1. **It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.**
2. **The certificate remains valid until the manufacturing conditions with applicable CE Requirement or the quality systems are changed.**
3. **The certificate validity is conditioned by positive results or surveillance audits.**
4. **After fulfilling the relevant EU legislation and CE Requirement, the manufacturer shall affix to each device, of the referenced models.**
5. **The CE Certificate as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives with EN standard requirement. 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.ukglobals.uk/Verify

Date of Certification	09 April. 2021
1 st Surveillance Audit	08 April. 2022
2 nd Surveillance Audit	08 April. 2023
Certificate Expiry (subject to the company maintaining its system to the required standard)	08 April. 2024

Authorised Signatory

CE

This certificate is the property of UK Global Certification & Inspection Limited and shall be returned immediately on request.
2nd Floor College House, 17 King Edwards Road, Ruislip, London, HA 47 AE, United Kingdom
Website:- www.ukglobals.uk, enquiries@ukglobals.uk
Company No. 12654562

UK Global Certification & Inspection Limited