Issued to:

Guilin HBM Health Protection, Inc.
No.1-2 Shuijing East Road
Economic Development Zone
Guilin City
China

Notified Body: 2777

SATRA customer number: P20293

EU Type-Examination Certificate

Certificate number: 2777/15894-02/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

MSG7255	Size 5.5
MSG7260	Size 6.0
MSG7265	Size 6.5
MSG7270	Size 7.0
MSG7275	Size 7.5
MSG7280	Size 8.0
MSG7285	Size 8.5
MSG7290	Size 9.0

Description:

Sterile Latex Surgical Gloves

Classification:

	EN ISO 374-1:2016+A1:2018 Type B	**Level**	**EN 374-4:2019 Degradation**
K	40% Sodium Hydroxide	6	-6.0%
P	30% Hydrogen Peroxide	6	-2.1%
T	37% Formaldehyde	6	-19.1%
	EN ISO 375-5:2016		
	Resistance to Bacteria and Fungi	Pass	
	Resistance to Virus	Pass	

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA- CHM0301662/2034/LH/A/Final, CHM0301662/2034/LH/C, CHM0301662/2034/SPT, CHM0301662/2034/LH/B/Final, SPC0309209/2111

Signed on behalf of SATRA:

Quincey Brown

Date first issued: 25/02/2021
Date of issue: 06/04/2021
Expiry date: 25/02/2026

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.

Declaration of Conformity

MANUFACTURER
(name and address): Guilin HBM Health Protections,Inc.
No.1-2, Shuijing East Road, Economic and Technological Development Area, Guilin,China

AUTHORIZED REPRESENTATIVE
(name and address): HBM Medical
Coliemore House, Coliemore Road, Dalkey, Co. Dublin, Ireland.

PRODUCTS:

Product Name	Product REF Number	Description	Classification
Sterile Latex Surgical Gloves Meditrade Gentle Skin® Superior OP	*MSG7255 = 904155* *MSG7260 = 904160* *MSG7265 = 904165* *MSG7270 = 904170* *MSG7275 = 904175* *MSG7280 = 904180* *MSG7285 = 904185* *MSG7290 = 904190*	Latex Surgical Gloves, Sterile, Disposables, Powder Free	CAT III; according to PPE regulations 2016/425 of Annex II

CONFORMITY ASSESSMENT ROUTE: EU Regulation 2016/425.

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of EN ISO 21420:2020 + A1:2009, EN ISO 374-1:2016 + A1:2018, EN ISO 374- 5:2016 for EU Type Examination (Module B) All supporting documentation is retained at the premises of the manufacturer.

PPE is subject to the following conformity assessment procedure by the notified body (SATRA, 2777): Conformity to type based on quality assurance of the production process (module C2) according to Annex VII.

STANDARDS APPLIED: Applied standards are listed in the Essential Requirements Checklist

NOTIFIED BODY: SATRA Technology Europe Limited
Bracetown Business Park
Clonee,
D15 YN2P, Ireland.

EC CERTIFICATE: Notified body number: 2777

DESIGN EXAMINATION CERTIFICATE: 2777/15894-02/E00-00

Place, Date of issue: Guilin, 2022-02-10

SIGNATURE:

Tiger Liu General Manager
For and on behalf of Guilin HBM Health Protections,Inc.

Pu Lei

Pu Lei Quality director
Regulatory Affairs Supervisor
For and on behalf of Guilin HBM Health Protections,Inc.