# 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<br><br>Meditrade Gentle Skin® Superior OP | *MSG7255 = 904155*<br>*MSG7260 = 904160*<br>*MSG7265 = 904165*<br>*MSG7270 = 904170*<br>*MSG7275 = 904175*<br>*MSG7280 = 904180*<br>*MSG7285 = 904185*<br>*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.



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