

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

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 Pu 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.

GUILIN HBM HEALTH PROTECTIONS, INC.

桂林恒保健康防护有限公司

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