

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 Number	Description	GMDN Code	Classification
<i>Medline Signature OR</i>	<i>MSG7255,MSG7260,MSG7265, MSG7270,MSG7275,MSG7280,</i>	Surgical gloves	/	CAT III; 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.

STANDARDS APPLIED:

Applied standards are listed in the Essential Requirements Checklist

NOTIFIED BODY:

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

Notified body number: 2777

EC CERTIFICATE:


DESIGN EXAMINATION CERTIFICATE: 2777/15894-01/E00-00

START OF PPE MARKING:

Product Name	Product Number	Date of First PPE Marking	First Batch Manufactured under Current Notified Body Number
<i>Medline Signature OR</i>	<i>Medline Signature OR</i>	16 June,2020	GUIL20W47

Place, Date of issue: Guilin, 2021-03-02

SIGNATURE:


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





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