

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	CND Code	Classification
Medispo® Premium	MPIG55, MPIG60, MPIG65, MPIG70, MPIG75, MPIG80, MPIG85, MPIG90, MPUG55, MPUG60, MPUG65, MPUG70, MPUG75, MPUG80, MPUG85, MPUG90 MPUG55, MPUG60, MPUG65, MPUG70, MPUG75, MPUG80, MPUG85, MPUG90 MPOG55, MPOG60, MPOG65, MPOG70, MPOG75, MPOG80, MPOG85, MPOG90	Surgical gloves, sterile; model: natural rubber, powder-free Beaded and Non-beaded Creamy white, green and brown color	code: T01010102	MDR: Rule 7, Class II a, according to annex VIII of directive EU 2017/745 PPE CAT III; PPE REGULATIONS 2016/425 of Annex II

We herewith declare under our sole responsibility that the above-mentioned products:

are in conformity with Annexes II and III of Regulation (EU) 2017/745 / according to Article 52(7) of Regulation (EU) 2017/745
 and

are in conformity with Personal Protective Equipment Regulation (EU) 2016/425, under Category III risk set out
 in Annex I, meeting the provisions of EN ISO 21420:2020 + A1:2009, EN ISO 374-1:2016 + A1:2018, EN ISO
 374-2:2019, EN ISO 374-4:2019, 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:	MDR: BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands CE 2797
	PPE: BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands NUMBER: 2797 SATRA Technology Europe Limited Bracetown Business Park Clonee, D15 YN2P, Ireland NUMBER: 2777 CERTIFICATE : EU type-examination through Module B
CERTIFICATES:	MDR: BSI Group The Netherlands B.V CE NUMBER: 2797 Certificate number: 747912 R000

PPE:

SATRA Technology Europe Limited

NUMBER: 2777

Certificate number : 2777 / 23740-01 / E00-00

Manufacturing plant surveillance through Module D:

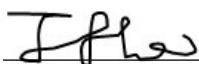
NOTIFIED BODY: BSI Group The Netherlands B.V.

NUMBER: 2797

Certificate number: CE 754434

Place, Date of issue: Guilin, 2021-04-08

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.

