

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® Essential	MLE55, MLE60 MLE65, MLE70 MLE75, MLE80 MLE85, MLE90	Surgical gloves, sterile; model: Latex powder-free Beaded and Non-beaded Creamy white color	code: T01010102	MDR: Rule 7, Class II a, according to annex VIII of Regulation EU 2017/745 PPE CAT III; PPE REGULATIONS 2016/425 of Annex II

You have to add UDI-DI in the certificate of conformity

We need to also mention on declaration the purpose intended use

The BSI Certificate says Regulation (EU) 2017/745, Annex IX chapter I and III

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).

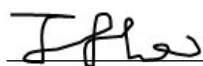
All supporting documentation is retained at the premises of the manufacturer.

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: 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
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Place, Date of issue: Guilin, 2023-03-21

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.

