

## 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
DOMETRA®	8956583 8956584 8956585 8956586 8956587 8956588 8956589 8956590	Surgical gloves, sterile; model: natural rubber, powder-free	code: T01010102	<b>MDR:</b> Rule 7, Class II a, according to annex VIII of Regulation EU 2017/745
		Beaded and Non-beaded Creamy white, green and brown color		<b>PPE</b> CAT III; PPE REGULATIONS 2016/425 of Annex II

Basic UDI-DI: 697178707SGNRUF

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).

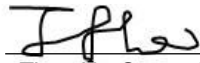
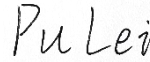
All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED:	Applied standards are listed in the Essential Requirements Checklist
NOTIFIED BODY:	<b>MDR:</b> BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands CE 2797
	<b>PPE:</b> SATRA Technology Europe Limited Bracetown Business Park Clonee, D15 YN2P, Ireland NUMBER: 2777 CERTIFICATE : EU type-examination through Module B
CERTIFICATES:	<b>MDR:</b> BSI Group The Netherlands B.V CE NUMBER: 2797 Certificate number: 747912 R000 <b>PPE:</b> SATRA Technology Europe Limited NUMBER: 2777 Certificate number: 2777 / 18178-05 / E00-00 Manufacturing plant surveillance through Module D: NOTIFIED BODY: SATRA Technology Europe Limited

	NUMBER: 2777 Certificate number: STE4810Z2S7
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Place, Date of issue: Guilin, 2025-03-24

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.