

EU DECLARATION OF CONFORMITY

Manufacturer	Guilin HBM Health Protections Inc. No. 1-2, Shuijing East Road Economic & Technological Development Area 541805 Guilin, Guangxi, China
Manufacturer SRN	CN-MF-000033439
European Authorized Representative	HBM Medical Coliemoore House, Coliemoore Road Dalkey, Co Dublin A96 A8D5 Ireland
European Authorized Representative SRN	IE-AR-000031279
Product description	surgical and protective, latex, powder-free gloves, sterile, for single use
Brand name	dermagel basic
Reference numbers	RC100820 55-90_2937
Product code	MLES55/60/65/70/75/80/85/90
Sizes	5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
Basic UDI-DI code	697178707SGNRUF
EMDN Code	T01010102
Intended use	Sterile, surgical and protective gloves intended to be worn on hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment during surgical procedure. Chemo-risk gloves designed for protection while working with the administration of chemotherapy drugs. Single use.
MDR classification	class IIa, Rule 6 according to Annex VIII of Regulation (EU) 2017/745
Conformity assessment procedure (MDR)	Annex IX, Chapter I and III
Notified Body (MDR)	BSI Group The Netherlands B.V., Notified Body No 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
CE Certificate number (MDR)	MDR 747912 R000
PPER classification	category III
Conformity assessment procedure (PPER)	EU Type-examination (Module B), Annex V & Module D, Annex VIII
EU Type-examination certificate notified body (PPER)	ANCCP Certification Agency Srl, Notified Body No 0302 Via Dello Struggino, 6 57121 – Livorno, Italy
EU Type-examination certificate number (PPER)	PPE-2425-23213-Cert

We, HBM Guilin Health Protections Inc., herewith declare under our own responsibility that above mentioned product:

1. is in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;
2. is in conformity with Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC;

3. is the subject to the EU Type certificate (Module B) number PPE-2425-23213-Cert, issued by notified body ANCCP Certification Agency Srl, No 0302, Via Dello Struggino, 6, 57121 – Livorno, Italy;
4. is the subject to the conformity assessment procedure to type based on conformity to type based on quality assurance of the production process (Module D) under surveillance of the notified body Satra Technology Europe Ltd, No 2777, Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland;

Applicable standards:

No	Standard	No	Standard
1	EN ISO 13485:2016	22	EN ISO 21420:2020
2	EN 455-1:2020+A2:2024	23	EN ISO 374-1:2016 + A1:2018
3	EN 455-2:2024	24	EN ISO 374-2:2019
4	EN 455-3:2023	25	EN ISO 374-4:2019
5	EN 455-4:2009	26	EN ISO 374- 5:2016
6	EN ISO 14971:2019+A11:2021	27	EN 16523-1:2015+A1:2018
7	EN ISO 15223-1:2021		
8	EN ISO 20417:2021		
9	ISO 2859-1:1999+A1:2011		
10	EN ISO 10993-1:2020		
11	EN ISO 10993-5:2009		
12	EN ISO 10993-10:2023		
13	EN ISO 10993-11:2018		
14	EN ISO 10993-23:2021		
15	EN 556-1:2024		
16	EN ISO 11737-1:2018/A1:2021		
17	EN ISO 11737-2:2020		
18	EN ISO 11137-1:2015/A2:2019		
19	EN ISO 11137-2:2015/A1:2023		
20	EN ISO 11607-1:2020/A1:2023		
21	EN ISO 11607-2:2020/A1:2023		

Signed on behalf of the manufacturer:

Place, Date of issue: Guilin, April.07, 2025

Signature:

Name and position: Chengmin Wang R&D Department Manager

