EC DECLARATION OF CONFORMITY

REGULATION 745/2017 ON MEDICAL DEVICE

Name and address of the manufacturer: /	Guilin HBM Health Protections, Inc. No.1-2, Shuijing East Road, Economic and Technological Development Area, 541805 Guilin, Guangxi, China
EC Authorized Representative:/	HBM Medical Coliemore House, Coliemore Roud, Dalkey, Co Dublin, A96 A8D5, Ireland

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device meets the provisions of Medical Device Regulation of EU 2017/745:2017 and their transpositions into national laws which apply to the device. All supporting documentations are retained under the premises of this manufacturer.

Name of the medical device: /	Medispo® Premium Polyisoprene Surgical Gloves
Model: /	Powder-free Textured Cuffed Polyisoprene Rubber Powder-free Textured Uncuffed Polyisoprene Rubber Powder-free Smooth Cuffed Polyisoprene Rubber Powder-free Smooth Uncuffed Polyisoprene Rubber
Color:	Cream, brown, green, blue
Size:	5.5, 6, 6.5, 7,7.5, 8, 8.5 ,9, 9.5.
UMDNS Code:/	11883
Basic UDI-DI:/	697178707SGPIU3
Intended purpose：/	The surgical gloves are sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.
Classification/	Rule 7, Class Ⅱa, according to annex VIII of directive EU 2017/745(MDR) / CND code: T01010203 SURGICAL GLOVES, POLYISOPRENE
Conformity assessment: /	Declare the conformity of the above mentioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 / according to Article 52(7) of Regulation (EU) 2017/745 /
Notified Body: /	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands CE 2797
Registration No.: /	MDR 747912 R000

Meets the provisions of the Regulation EU 2017/745(MDR) which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Place & Date	Name & Title
Guilin HBM Health Protections, Inc. Oct. 8th, 2024	Signature: _____, QMR

GUILIN HBM HEALTH PROTECTIONS, INC.

Lists of Applicable Regulation and Standards

(Harmonized standards, international standards, partly applicable standards)

Relevant standards applied to the device are listed as follows:

No.	Standards	Reference	Content
1.	MDR (EU) 2017/745	2017	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.	MEDDEV2.7.1	Rev4	Clinical Evaluation : A guide for manufacturers and notified bodies under directives
3.	MEDDEV 2.12/2 Rev 2	2012	Guidelines on post market clinical follow-up
4.	MEDDEV 2.12/1 Rev 8	2013	Guidelines on a medical devices vigilance system
5.	MDCG 2020-6	2020	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
6.	MDCG 2020-8	2020	Post-market clinical follow-up (PMCF) Evaluation Report Template
7.	EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
8.	EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
9.	ISO 10993-1	2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
10.	ISO 10993-4	2017	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood
11.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

12.	EN ISO 10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
13.	EN ISO 10993-11	2017	Biocompatibility Evaluation of Medical Device - Part 11: Tests for systemic toxicity
14.	EN 62366-1	2015	Medical devices — Part 1: Application of usability engineering to medical devices
15.	EN ISO 13485	2016	Medical devices-Quality management systems-Requirements for regulatory purpose
16.	EN 455-1	2020	Medical gloves for single use -Part 1: Requirements and testing for freedom from holes
17.	EN 455-2	2015	Medical gloves for single use Part 2: Requirements and testing for physical properties
18.	EN 455-3	2015	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
19.	EN 455-4	2009	Medical gloves for single use Part 4: Requirements and testing for shelf life determination
20.	ISO 11607-1	2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
21.	ISO 11607-2	2019	Validation requirements for forming, sealing and assembly processes
22.	ISO 11737-1	2018	Sterilization of medical devices —Microbiological methods —Part 1: Determination of a population of microorganisms on products
23.	ISO 11737-2	2020	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
24.	EN ISO 11137-1	2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
25.	ISO 11137-2	2015	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose
26.	ISO 11137-3	2017	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control
27.	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments —Part 1: Classification of air cleanliness
28.	EN ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
29.	EN 868-1	1997	Packaging materials and systems for medical devices which are to be sterilized - Part 1:General

			requirements and test methods
30.	EN 868-5	2018	Packaging materials and systems for medical devices which are to be sterilized - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods