EC DECLARATION OF CONFORMITY

REGULATION 2017/745 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	Brand Name	Sizes	Classification
Natural Rubber Latex Surgical Gloves	Medispo	5.5/6.0/6.5/7/7.5/8/8.5/9.0/9.5	Class IIa

UMDNS Code:/ 11883

Basic UDI-DI:/ 697178707SGNRUF

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:
T01010102, SURGICAL GLOVES, LATEX, NON-POWDERED

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 Annex IX chapter I and III,Annex IX Chapter II 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.

Guilin 30/10/2022
Place, date

Pu Lei
Pu lei/Quality Director Name and Position