DECLARATION OF CONFORMITY

REGULATION (EU) 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 SRN: CN-MF-000033439
EU Authorized Representative:	Continental Medical B.V. Strevelsweg 700 303 Unit E7288, 3083AS Rotterdam SRN: NL-AR-000022261

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

Device name:	Powder free natural rubber latex surgical gloves
Model:	Powder-free Textured Cuffed Natural Rubber Powder-free Textured Uncuffed Natural Rubber Powder-free Smooth Cuffed Natural Rubber Powder-free Smooth Uncuffed Natural Rubber
Color:	Cream, brown, green
Size:	5.5, 6, 6.5, 7,7.5, 8, 8.5 ,9, 9.5
EMDN Code:	T01010102
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:	Class IIa, Rule 7, according to annex VIII of Regulation(EU) 2017/745
Conformity assessment:	Regulation(EU) 2017/745 Annex IX Chapter I and III
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 Regulation (EU) 2017/745 which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Place, date	Name and function
Guilin HBM Health Protections, Inc. 2025.10.28	Signature: Huang Shun, PRRC