EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747912 R000

Manufacturer: Guilin HBM Health Protections, Inc.

Address:
No.1-2, Shuijing East Road
Economic & Technological
Development Area
Guilin
Guangxi
541805
China

Single Registration Number: CN-MF-000033439

EU Authorised Representative: HBM Medical

Address:
Coliemore House
Coliemore Road
Dalkey
Co Dublin
A96 A8D5
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-05-12**

Current Issue Date: **2024-02-15**

Starting Validity Date: **2024-02-15**

Expiry Date: **2027-05-11**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Natural rubber latex lubricated male condoms	Condom is used for contraception and prevention of sexually transmitted diseases

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Powder free natural rubber latex surgical gloves	Class IIa
Powder free synthetic polyisoprene surgical gloves	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-05-12	3415375	Issued
2023-09-28	30001914	Amended – addition of critical sub-contractor for E beam sterilization
Current	30092918	Supplemented – Addition of Natural rubber latex lubricated male condom device

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