EU Quality Management System Certificate

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

MDR 736670 R000

Manufacturer: Shenzhen HugeMed Medical Technical Development Co.,Ltd.

Address:
416-1, 516-1, Building 2, No. 1, Mawu Road,
Baoan Community,
Yuanshan Street,
Longgang District,
Shenzhen
Guangdong
518115
China

Single Registration Number: CN-MF-000010895

EU Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)

Address:
Eiffestrasse 80
20537 Hamburg
Germany

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 and Class IIb implantable devices an 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 Issued: **2021-12-06** Date: **2022-03-16** Expiry Date: **2026-12-05**

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

Device(s)	Risk Classification
Single Use Laryngoscope Blade	Class Is
Flexible Video Ureterorenoscope	Class IIa

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

First Issued: **2021-12-06** Date: **2022-03-16** Expiry Date: **2026-12-05**

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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
2021-12-06	3293896	Issued.
Current	3642475	Supplemented – Addition of Flexible Video Ureterorenoscope devices. Amended - Correction to Certificate expiry date to reflect 5 years

First Issued: **2021-12-06** Date: **2022-03-16** Expiry Date: **2026-12-05**

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

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 736670 R000

Date: **2022-03-16**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Shenzhen King Medical Packaging Sterilization Service Co., Ltd 201C, Building 4, Jinxiudadi No. 114 Hudipai, Guanghunan Dafu Community Longhua District Shenzhen City Guangdong Province 518000 People's Republic of China	**ETO Sterilization**

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