bsi.

By Royal Charter

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

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Date: 2023.06.10 09:57:11 EEST
Reason: MoldSign Signature
Location: Moldova

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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