CERTIFICATE OF FDA REGISTRATION

HEREBY CERTIFY THAT

Shenzhen HugeMed Medical Technical Development Co., LTD

HAS SUCESSFULLY COMPLETED THE FDA REGISTRATION

FOR

OWNER/OPERATOR NUMBER: 10052108

MDL	Product Code	510K ?	Class	GMP/UDI Exempt?	Device Name
D267908	CCW	Exempt	Class I	No.	Video Laryngoscope;VL3R / VL3D
D267909	LRC	Exempt	Class I	No.	Reusable Blade ;Disposable Blade ;B3R/B3D

FDA US AGENT

IRC USA
www.IRC-US.com

Charlie Mack

PRINCIPAL ENGINEER

CERTIFICATE NO.:IRC-SH-1606

IRC
www.IRC-US.com
Your Partner in Achieving FDA Compliance

Digitally signed by Ceaicovschi Tudor
Date: 2022.01.20 17:33:25 EET
Reason: MoldSign Signature
Location: Moldova

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Shenzhen HugeMed Medical Technical Development Co., Ltd.
6B Block A, Tempus Building
1st Qingshuihe Road
Luohu District
Shenzhen
Guangdong
518023
China

深圳市宏济医疗技术开发有限公司
中国
广东省
深圳市
罗湖区
清水河一路
腾邦大厦A栋6B
邮编：518023

Holds Certificate No: **MD 722076**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture and distribution of Flexible Video Ureterorenoscope, Video Laryngoscope and Single Use Laryngoscope Blade.
电子膀胱肾盂镜，麻醉视频喉镜，一次性使用视频喉镜片的设计、生产和销售。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-12-22
Latest Revision Date: 2020-12-22

Effective Date: 2020-12-22
Expiry Date: 2023-12-21

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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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-12-06** Date: **2021-12-06** Expiry Date: **2024-12-05**

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