

# CERTIFICATE OF FDA REGISTRATION



HEREBY CERTIFY THAT

**Shenzhen HugeMed Medical  
Technical Development Co., LTD**

FDA US AGENT

**IRC USA**  
www.IRC-US.com

**HAS SUCESSFULLY COMPLETED  
THE FDA REGISTRATION**

**FOR**

**OWNER/OPERATOR NUMBER: 10052108**

*Charlie Mack*

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

**PRINCIPAL ENGINEER**

**CERTIFICATE NO.:IRC-SH-1606**



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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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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](https://www.bsi-global.com/ClientDirectory).  
Printed copies can be validated at [www.bsi-global.com/ClientDirectory](https://www.bsi-global.com/ClientDirectory) or telephone +86 10 8507 3000.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 845 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
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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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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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