



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

中国作家湖下河湖区

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。

Gange Stade

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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...making excellence a habit."

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Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Certificate No: MD 722076

Location

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

Shenzhen HugeMed Medical Technical

Development Co., Ltd. 416-1, 516-1, Building 2

No. 1, Mawu Road, Baoan Community, Yuanshan Street

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Shenzhen Guangdong 518115 China

深圳市宏济医疗技术开发有限公司

中国 广东省

深圳市 龙岗区

园山街道保安社区

马五路1号2栋416-1、516-1

邮编: 518115

Registered Activities

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销售。

Design and manufacture 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和生产。

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