

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: **Henan Robestain Medical Products Co., Ltd.**
No.590, Zhangnan Industry Zone
Zhangsanzhai Town
Changyuan City
Henan
453400
China

河南省荣贝得医疗器械有限公司
中国
河南省
长垣市
张三寨镇
张南村工业区590号
邮编：453400

Holds Certificate No: **MD 731767**

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

The manufacture and distribution of sterile Disposable Medical Face Mask, Disposable Surgical Gown, Disposable Surgical Drapes, Surgical Packs, Disposable Medical Caps and non-sterile Equipment Covers, Disposable Medical Protective Suits, Disposable Scrub Suits, Disposable Isolation Gowns, Disposable Shoe Covers. Provision of contract ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.

一次性使用医用口罩、一次性使用手术衣、一次性使用手术单、一次性使用手术包、一次性使用医用帽、非无菌器械罩、一次性使用医用防护服、一次性使用洗手衣、一次性使用隔离衣、一次性使用鞋套的制造和销售。根据EN ISO 11135:2014相关的质量管理体系要求提供环氧乙烷灭菌服务。

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-10-29

Effective Date: 2023-10-29

Latest Revision Date: 2023-10-09

Expiry Date: 2026-10-28



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