



Certificate of Registration

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

This is to certify that: GAUKE Healthcare Co., Ltd

Chengnan Industrial Park

TuangFeng County

Huang Gang

Hubei 438800 China 湖北高德急救防护用品有限公司

中国

湖北省 黄冈

团风具

城南工业区

邮编: 438800

Holds Certificate No: MD 722209

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

Design and Development, Manufacture and Distribution of Medical Gauze Swabs/Lap Sponges with X-ray Detectable, Medical Gauze Swabs /Gauze Balls, Absorbent Cotton Rolls/Cotton Balls/Cotton, Non-woven Sponges/Balls, First Aid Kits, Sterile Bandages, Sterile Dressings, Wound Plaster, Plaster of Paris Bandages, Disposable Medical Mask (in Sterile).

医用纱布片(带XR线)/医用腹部垫(带XR线),医用纱布片/医用纱布球,脱脂棉卷/脱脂棉球/脱脂棉,无纺布片/无纺布球,急救包,灭菌绷带,灭菌敷料,敷料贴,石膏绷带,一次性使用医用口罩(灭菌级)的设计开发、制造和分销。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-02-04 Effective Date: 2021-02-04 Latest Revision Date: 2021-02-04 Expiry Date: 2024-02-03

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...making excellence a habit."





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 <u>online</u>.

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