

Certificate of Registration

质量管理体系 – ISO 9001:2015

兹证明：
上海光电医用电子仪器有限公司
9131000060724188X6
中国
上海
奉贤区
上海市工业综合开发区内
环城北路567号
邮编：201401

Shanghai Kohden Medical
Electronic Instrument Corp.
No. 567 Huancheng Bei Road
Shanghai Comprehensive Industrial
Development Zone
Fengxian District
Shanghai
201401
China

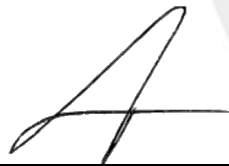
持有证书：**FM 595986**

并运行符合 ISO 9001:2015 要求的质量管理体系，认证范围如下：

患者监护仪、中央监护系统、心电图机及医疗器械软件的设计、开发、生产及售后服务。血细胞分析仪和特定蛋白测定仪的生产及售后服务。用于血细胞分析和特定蛋白分析的体外诊断试剂的生产和销售。除颤监护仪的生产及售后服务。

The design, development, manufacture and service provision of patient monitoring systems, central patient monitoring systems, electrocardiographs and medical device software. The manufacture and service provision of fully-automatic blood cell analyzers and specific protein analyzers. The manufacture and distribution of in-vitro diagnostic reagents for hematology testing and specific protein testing. The manufacture and service provision of defibrillator.

BSI代表：



Chris Cheung, 亚太地区 合规风险主管

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BSI保证英国有限公司，注册地英国，注册号码7805321，地址：389 Chiswick High Road, London W4 4AL, UK

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BSI集团公司成员。

持有证书:

FM 595986

地点

认证活动

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患者监护仪、中央监护系统、心电图机及医疗器械软件的设计、开发及售后服务。血细胞分析仪和特定蛋白测定仪的售后服务。用于血细胞分析和特定蛋白分析的体外诊断试剂的销售。除颤监护仪的售后服务。The design, development and service provision of patient monitoring systems, central patient monitoring systems, electrocardiographs and medical device software. The service provision of fully-automatic blood cell analyzers and specific protein analyzers. The distribution of in-vitro diagnostic reagents for hematology testing and specific protein testing. The service provision of defibrillator.

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BSI集团公司成员。

Certificate of Registration

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

This is to certify that: Shanghai Kohden Medical
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环城北路567号
邮编: 201401

Holds Certificate No: **MD 585402**

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

The design, development, manufacture and service provision of patient monitoring systems, central patient monitoring systems, electrocardiographs and medical device software. The manufacture and service provision of fully-automatic blood cell analyzers and specific protein analyzers. The manufacture and distribution of in-vitro diagnostic reagents for hematology testing and specific protein testing. The manufacture and service provision of defibrillator.

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For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2012-05-23

Latest Revision Date: 2021-04-29

Effective Date: 2021-05-22

Expiry Date: 2024-05-21



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邮编: 200233

Registered Activities

The manufacture of patient monitoring systems, central patient monitoring systems, electrocardiographs and medical device software. The manufacture of fully-automatic blood cell analyzers and specific protein analyzers. The manufacture of in-vitro diagnostic reagents for hematology testing and specific protein testing. The manufacture of defibrillator.
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