

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

质量管理体系 ISO 13485:2016

This is to certify that: CARETIUM MEDICAL INSTRUMENTS CO., LTD
兹证明 7 th Floor Building 1
Beishan Industrial Park, Beishan Road
Yantian
Shenzhen
Guangdong
518083
China
深圳市凯特生物医疗电子科技有限公司
91440300734144898T
中国
广东省
深圳市
盐田区
北山道北山工业区
1栋7楼
邮编: 518083

Holds Certificate No: **MD 748284**
持有证书

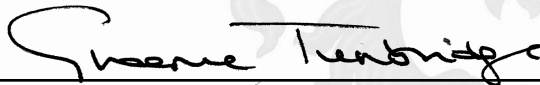
and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

并运行符合 ISO 13485:2016 要求的质量管理体系, 认证范围如下:

Design, manufacture, distribution, maintenance and repair of IVD instruments and the design, manufacture and distribution of reagents used in clinical diagnostics. Manufacture of Electrolyte module for Automatic biochemical analyzer. Design, development, manufacture and distribution of cleaning solution and urine diluent for Electrolyte analyzer

临床诊断用体外诊断仪器的设计、制造、分销、维护和维修以及试剂的设计、制造和分销。全自动生化分析仪用电解质模块的生产。电解质分析仪用清洗液和尿液稀释液的设计、开发、制造、分销。

For and on behalf of BSI:
BSI代表:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date 首次发证日期: 2021-11-17

Effective Date 生效日期: 2024-11-17

Latest Revision Date 最新发证日期: 2024-10-24

Expiry Date 有效期至: 2027-11-16



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The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration (www.cnca.gov.cn)

本证书信息亦可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。

The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.

获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

Information and Contact: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

信息查询及联系方式: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | 电话: +31 20 3460 780 BSI集团荷兰有限公司, 注册地荷兰, 注册号 33264284 | BSI集团控股有限公司成员

China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部 (北京): 北京市建国门外大街24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。

Certificate No. **MD 748284**
持有证书:

Location 地点

Registered Activities 认证活动

CARETIUM MEDICAL INSTRUMENTS CO., LTD
7 th Floor Building 1
Beishan Industrial Park, Beishan Road
Yantian
Shenzhen
Guangdong
518083
China

深圳市凯特生物医疗电子科技有限公司
91440300734144898T
中国
广东省
深圳市
盐田区
北山道北山工业区
1栋7楼
邮编: 518083

Design, manufacture, distribution, maintenance and repair of
IVD instruments used in clinical diagnostics.
临床诊断用体外诊断仪器的设计、制造、分销、维护和维修。

CARETIUM MEDICAL INSTRUMENTS CO., LTD
4th Floor Building 1
Beishan Industrial Park, Beishan Road
Yantian
Shenzhen
Guangdong
518083
China

深圳市凯特生物医疗电子科技有限公司
91440300734144898T
中国
广东省
深圳市
盐田区
北山道北山工业区
1栋4楼
邮编: 518083

Design, manufacture, and distribution of IVD reagents used
in clinical diagnostics.
临床诊断用体外诊断试剂的设计、制造和分销。

Original Registration Date 首次发证日期: 2021-11-17

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1栋8楼西侧
邮编: 518083

Registered Activities 认证活动

Manufacture of Electrolyte module for Automatic biochemical analyzer. Design, development, manufacture and distribution of cleaning solution and urine diluent for Electrolyte analyzer. Manufacture of reagent for Electrolyte analyzer.
全自动生化分析仪用电解质模块的生产。电解质分析仪用清洗液和尿液稀释液的设计、开发、制造、分销。电解质分析仪用试剂的生产。



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