

Certificate of Registration

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

持有证书 ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Zhejiang POCTech Co., Ltd.
兹证明 No.1633 Hongfeng Road
Building 11 & 12
Huzhou City
Zhejiang
313000, China

浙江凯立特医疗器械有限公司
91330500558634897J
中国
浙江省
湖州市
红丰路1633号
11、12幢
邮编：313000

Holds Certificate No: **MD 714248**
持有证书

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

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

The design, development, manufacture and distribution of continuous glucose monitoring systems and related sterile and non-sterile accessories. The design, development, manufacture and delivery of mobile software applications related with continuous glucose monitoring systems.

持续葡萄糖监测系统及相关无菌/非无菌附件的设计开发、制造以及分销。与持续葡萄糖监测系统相关的移动软件应用的设计开发、制造与交付。

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： 2019-10-25

Effective Date 生效日期： 2025-10-25

Latest Revision Date 最新发证日期： 2025-08-29

Expiry Date 有效期至： 2028-10-24



Page: 1 of 1

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. 此证书的所有权属于BSI并受合同条款的约束

An electronic certificate can be authenticated [online](#). 可以 [在线](#) 查询电子证书的有效性。

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

打印的证书可以通过网站 <http://www.bsi-global.com/ClientDirectory> 或者致电 +86 10 8507 3000 查询。

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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000

BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.

信息查询及联系方式: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. 电话: + 44 345 080 9000 BSI保证英国有限公司, 注册地英国, 注册号码7805321, 地址:

Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.

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

市建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。