

**GIẤY CHỨNG NHẬN ISO 13485**  
*Tài liệu được xác nhận bằng chữ ký số*

*Hà Nội, ngày 28 tháng 05 năm 2022*  
**Người đại diện hợp pháp của cơ sở**

**GIÁM ĐỐC**  
**Nguyễn Thị Kim Chi**

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**Beckman Coulter Laboratory  
Systems (Suzhou)Co., Ltd.  
No. 181, West Su Hong Road  
Suzhou Industrial Park  
Suzhou  
Jiangsu  
215021  
China**

贝克曼库尔特实验系统（苏州）有限公司  
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苏虹西路181号  
邮编：215021

Holds Certificate No: **MD 733707**

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

The development of the application for AU in-vitro diagnostic reagents on AU platform. The design, manufacture and distribution of in-vitro diagnostic reagents for immunoassay, clinical chemistry and hematology system. The design, manufacture of in-vitro diagnostic chemistry analyzers.

AU临床生化体外诊断试剂在AU平台应用的开发。

用于免疫测定，临床生化和血液学系统的体外诊断试剂的设计，制造和分销。

体外诊断化学分析仪的设计，制造。

For and on behalf of BSI:

**Gary E Slack, Senior Vice President - Medical Devices**

Original Registration Date: 2020-09-28

Latest Revision Date: 2020-09-28

Effective Date: 2020-09-28

**Expiry Date: 2023-09-27**

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