



**GIẤY CHỨNG NHẬN ĐẠT TIÊU CHUẨN QUẢN LÝ CHẤT LƯỢNG
ISO 13485**

Cơ sở đăng ký lưu hành trang thiết bị y tế: **VĂN PHÒNG ĐẠI DIỆN BECKMAN COULTER
HONG KONG LIMITED TẠI THÀNH PHỐ HỒ CHÍ MINH**

Địa chỉ: Phòng 1906, Lầu 19, Tòa nhà Maple Tree Business Centre, Số 1060, Đường Nguyễn
Văn Linh, Phường Tân Phong, Quận 7, TPHCM

Xác nhận tài liệu đính kèm.

TPHCM, Ngày 28 tháng 06 năm 2022

Người đại diện hợp pháp của cơ sở

Ký tên



Phạm Mạnh Tuấn

Trưởng Văn Phòng Đại Diện

Certificate of Registration

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

This is to certify that:

Beckman Coulter, Inc.
250 South Kraemer Blvd.
Brea
California
92821
USA

Holds Certificate Number:

MD 670607

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 and development, manufacture, distribution, installation, service and customer support of automated instruments, software, reagents, calibrators, controls and other consumables for use in in-vitro diagnostic medical devices

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-04-12

Latest Revision Date: 2021-09-08

Effective Date: 2021-03-19

Expiry Date: 2024-03-18

Page: 1 of 3



...making excellence a habit.™

Certificate No: **MD 670607**

Location	Registered Activities
Beckman Coulter, Inc. 250 South Kraemer Blvd. Brea California 92821 USA	Design and development, manufacture, distribution, installation, service and customer support.
Beckman Coulter, Inc. 1000 Lake Hazeltine Drive Chaska Minnesota 55318 USA	Design and development, manufacture, distribution, installation, service and customer support.
Beckman Coulter, Inc. 2470 Faraday Avenue Carlsbad California 92010 USA	Design and development, manufacture and distribution.
Beckman Coulter, Inc. 2295 Progress Drive Hebron Kentucky 41048 USA	Warehouse and distribution
Beckman Coulter, Inc. 5355 West 76th Street Indianapolis Indiana 46268 USA	Manufacture of service parts and sub-assemblies.
Beckman Coulter, Inc. 5350 Lakeview Parkway South Drive Indianapolis Indiana 46268 USA	Customer Support

Original Registration Date: 2017-04-12

Latest Revision Date: 2021-09-08

Effective Date: 2021-03-19

Expiry Date: 2024-03-18

Page: 2 of 3

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 [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 670607**

Location	Registered Activities
Beckman Coulter, Inc. 11800 SW 147th Avenue Miami Florida 33196 USA	Design and development, manufacture, distribution, installation, service and customer support.
Beckman Coulter, Inc. 740 West 83rd Street Hialeah Florida 33014 USA	Manufacture and distribution.
Beckman Coulter Inc. 7381 Empire Drive Florence Kentucky 41042 USA	Manufacture
Beckman Coulter GmbH Europark Fichtenhain B13 47807 Krefeld Germany	Manufacture
Beckman Coulter, Inc. Microbiology Business 2040 Enterprise Blvd. West Sacramento California 95691 USA	Manufacture and distribution
Beckman Coulter, Inc. Microbiology Business 1584 Enterprise Blvd. West Sacramento California 95691 USA	Design and development, customer support and software

Original Registration Date: 2017-04-12

Latest Revision Date: 2021-09-08

Effective Date: 2021-03-19

Expiry Date: 2024-03-18

Page: 3 of 3

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 [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.