

# **Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng**

*Tài liệu được xác nhận bằng chữ ký số*

*Hà Nội, ngày 10 tháng 01 năm 2022*

**Người đại diện hợp pháp của cơ sở**

**Giám đốc  
Trịnh Diệu Hương**



# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Facility ID Number: F000075

Holds Certificate No:

**MDSAP 678344**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and development, manufacture, distribution, installation, and service 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: 2018-12-18

Effective Date: 2021-03-13

Expiry Date: 2022-03-12



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 4

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Certificate No: **MDSAP 678344**

Location	Registered Activities
Beckman Coulter, Inc. 250 South Kraemer Blvd. Brea California 92821 USA Facility ID Number: F000075	Design and development, manufacture, distribution, installation, service and customer support.
<b>Beckman Coulter, Inc.</b> 1000 Lake Hazeltine Drive Chaska Minnesota 55318 <b>USA</b> Facility ID Number: F001810	Design and development, manufacture, distribution, installation, service and customer support.
Beckman Coulter, Inc. 2470 Faraday Avenue Carlsbad California 92010 USA Facility ID Number: F001808	Design and development, manufacture and distribution.
Beckman Coulter, Inc. 2295 Progress Drive Hebron Kentucky 41048 USA Facility ID Number: F001805	Warehouse and Distribution.
Beckman Coulter, Inc. 5355 West 76th Street Indianapolis Indiana 46268 USA Facility ID Number: F001812	Manufacture of service parts and sub-assemblies.

Original Registration Date: 2018-12-18    Effective Date: 2021-03-13

**Expiry Date: 2022-03-12**

Page: 2 of 4

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 678344**

Location	Registered Activities
Beckman Coulter, Inc. 5350 Lakeview Parkway South Drive Indianapolis Indiana 46268 USA Facility ID Number: F001812	Customer Support.
Beckman Coulter, Inc. 11800 SW 147th Avenue Miami Florida 33196 USA Facility ID Number: F001809	Design and development, manufacture, distribution, installation, service and customer support.
Beckman Coulter, Inc. 740 West 83rd Street Hialeah Florida 33014 USA Facility ID Number: F001811	Manufacture and Distribution.
Beckman Coulter Inc. 7381 Empire Drive Florence Kentucky 41042 USA Facility ID Number: F001806	Manufacture
Beckman Coulter GmbH Europark Fichtenhain B13 47807 Krefeld Germany Facility ID Number: F003965	Manufacture

Original Registration Date: 2018-12-18

Effective Date: 2021-03-13

Expiry Date: 2022-03-12

Page: 3 of 4

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A Member of the BSI Group of Companies.

Certificate No: **MDSAP 678344**

Location

Beckman Coulter, Inc.  
Microbiology Business  
2040 Enterprise Blvd.  
West Sacramento  
California  
95691  
USA  
Facility ID Number: F001807

Registered Activities

Manufacture and distribution.

Beckman Coulter, Inc.  
Microbiology Business  
1584 Enterprise Blvd.  
West Sacramento  
California  
95691  
USA  
Facility ID Number: F001807

Design and development, customer support and software.



Original Registration Date: 2018-12-18

Effective Date: 2021-03-13

Expiry Date: 2022-03-12

Page: 4 of 4

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To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.



# Certificate of Registration

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

This is to certify that:

**Beckman Coulter Ireland Inc.**  
Lismeehan  
O'Callaghan's Mills  
Co. Clare  
**Ireland**

Holds Certificate Number:

**MD 670660**

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 clinical chemistry, haematology, heterogenous immunoassay and flow cytometry in vitro diagnostic devices.

For and on behalf of BSI:

\_\_\_\_\_  
Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-04-12

Latest Revision Date: 2021-08-17

Effective Date: 2021-11-21

**Expiry Date: 2022-05-20**

