

Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng ISO 13485

Tài liệu được xác nhận bằng chữ ký số và có hiệu lực kể từ ngày ký.

Hà Nội, ngày 10 tháng 8 năm 2019

Người đại diện hợp pháp của cơ sở

Xác nhận bằng chữ ký số

**Giám đốc
Trịnh Diệu Hương**

Giấy chứng nhận ISO của cơ sở sản xuất

CERTIFICAT

CERTIFICATE OF REGISTRATION



Système de Management de la Qualité / Quality Management System

bioMérieux, Inc.

1105 North Main Street
UNITED STATES - - LOMBARD, IL 60148

met en œuvre et entretient un **Système de Management de la Qualité**
conforme aux exigences de la norme
operates a Quality Management System which complies with the requirements of

ISO 9001:2015

Pour les activités suivantes / for the activities detailed below

Conception, fabrication et distribution de réactifs utilisés en laboratoires industriels

Design, manufacture, and distribution of reagents used in industrial laboratories

Site(s) de production ou d'activité / Operative unit(s)

bioMérieux, Inc. 1105 North Main Street, Lombard, Illinois 60148 USA

Etabli le
Issued on 14 septembre 2018
September 14th, 2018

Date début validité
Effective date 14 septembre 2018
September 14th, 2018

Valable jusqu'au
Expiry date 31 octobre 2019
October 31st, 2019

Numéro de certificat
Certificate number 32172 - 1

Pour le Directeur Certification
On behalf of the Certification Director



Thomas LOMMATZSCH

Responsable du Pôle Certification Instrumentation
Measuring Instruments Division Manager



Modifie le certificat 32172-0

Ce certificat est délivré conformément aux règles générales de certification LNE des systèmes de management d'entreprise.
This certificate is granted under the LNE regulations for registration.

Pour vérifier la validité du certificat :
To check the validity of the certificate :
Tel. : +33(0)1 40 43 37 30 - www.lne.fr



Laboratoire national de métrologie et d'essais
1, rue Gaston Boissier - 75724 PARIS Cedex 15

Giấy chứng nhận ISO của Chủ sở hữu sản phẩm



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 670623

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, development and manufacturing of in-vitro diagnostic test kits, reagents, instruments and software used in the diagnosis and management of disease status and transmissible agents.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-04-12

Latest Revision Date: 2018-11-28

Effective Date: 2019-01-01

Expiry Date: 2021-12-31

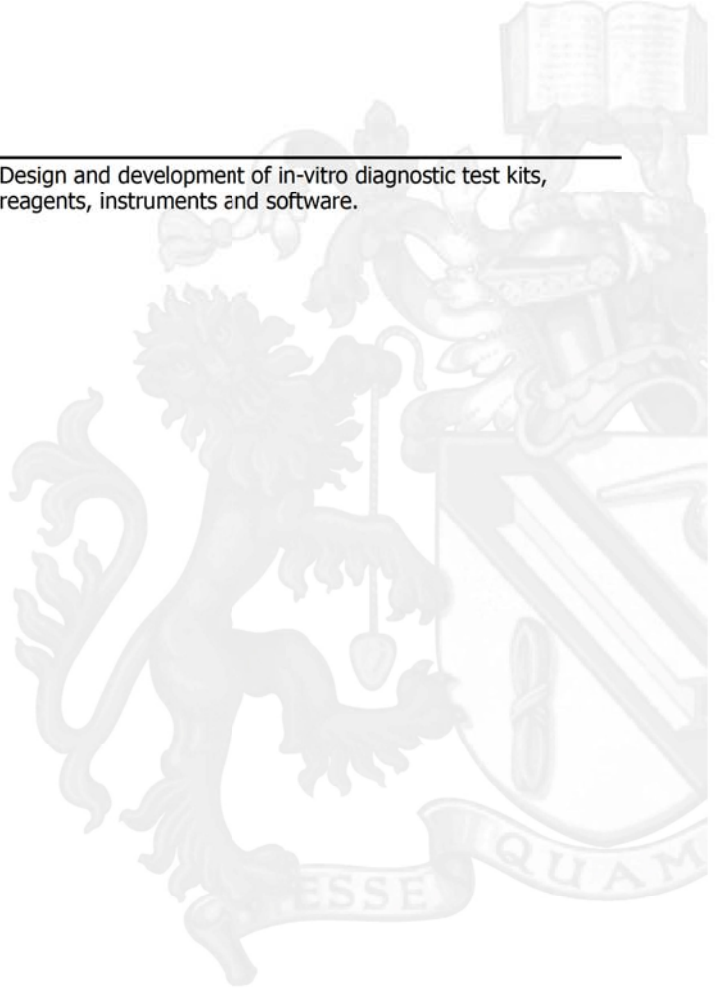
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...making excellence a habit.™

Certificate No: **MD 670623**

Location	Registered Activities
Beckman Coulter, Inc. 250 South Kraemer Blvd. Brea California 92821 USA	The design, development and manufacturing of in-vitro diagnostic test kits, reagents, instruments and software used in the diagnosis and management of disease status and transmissible agents.
Beckman Coulter, Inc. Microbiology Business 2040 Enterprise Blvd. West Sacramento California 95691 USA	Manufacturing of in-vitro diagnostic test kits and reagents.
Beckman Coulter, Inc. Microbiology Business 1584 Enterprise Blvd. West Sacramento California 95691 USA	Design and development of in-vitro diagnostic test kits, reagents, instruments and software.



Original Registration Date: 2017-04-12

Effective Date: 2019-01-01

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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

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