

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, Remanufacture, Service, Installation, and Distribution of Automated Instruments, Reagents, Calibrators, Controls, and other Consumables for use in In-Vitro Diagnostic Medical Devices.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-04-12

Latest Revision Date: 2018-03-02

Effective Date: 2018-03-19

Expiry Date: 2021-03-18

Page: 1 of 4



003

...making excellence a habit.™

Certificate No: MD 670607

Location	Registered Activities
Beckman Coulter, Inc. 250 South Kraemer Blvd. Brea California 92821 USA	Headquarters (Diagnostics Div.) Administration, Design and Development, Manufacturing and Remanufacture, Service (Technical Support Center), Distribution.
Beckman Coulter, Inc. 1000 Lake Hazeltine Drive Chaska Minnesota 55318 USA	Administration, Design and Development, Manufacturing, Service (Technical Support), Distribution.
Beckman Coulter, Inc. 2470 Faraday Avenue Carlsbad California 92010 USA	Manufacturing
Beckman Coulter, Inc. 2295 Progress Drive Hebron Kentucky 41048 USA	Distribution
Beckman Coulter, Inc. 322 Lake Hazeltine Drive Chaska Minnesota 55318 USA	Administration, Design and Development, Manufacturing, Service (Technical Support), Distribution.
Beckman Coulter, Inc. 312 Lake Hazeltine Drive Chaska Minnesota 55318 USA	Administration, Design and Development, Manufacturing, Service (Technical Support), Distribution.

Original Registration Date: 2017-04-12

Latest Revision Date: 2018-03-02

Effective Date: 2018-03-19

Expiry Date: 2021-03-18

Page: 2 of 4

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. 326 Lake Hazeltine Drive Chaska Minnesota 55318 USA	Administration, Design and Development, Manufacturing, Service (Technical Support), Distribution.
Beckman Coulter, Inc. 316 Lake Hazeltine Drive Chaska Minnesota 55318 USA	Administration, Design and Development, Manufacturing, Service (Technical Support), Distribution.
Beckman Coulter, Inc. 5355 West 76th Street Indianapolis Indiana 46268 USA	Installation, Service
Beckman Coulter, Inc. 5350 Lakeview Parkway South Drive Indianapolis Indiana 46268 USA	Service
Beckman Coulter, Inc. 11800 SW 147th Avenue Miami Florida 33196 USA	Administration, Design, Manufacturing, Service (Technical Support), Distribution
Beckman Coulter, Inc. 780 West 83rd Street Hialeah Florida 33014 USA	Distribution and Manufacturing

Original Registration Date: 2017-04-12

Latest Revision Date: 2018-03-02

Effective Date: 2018-03-19

Expiry Date: 2021-03-18

Page: 3 of 4

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

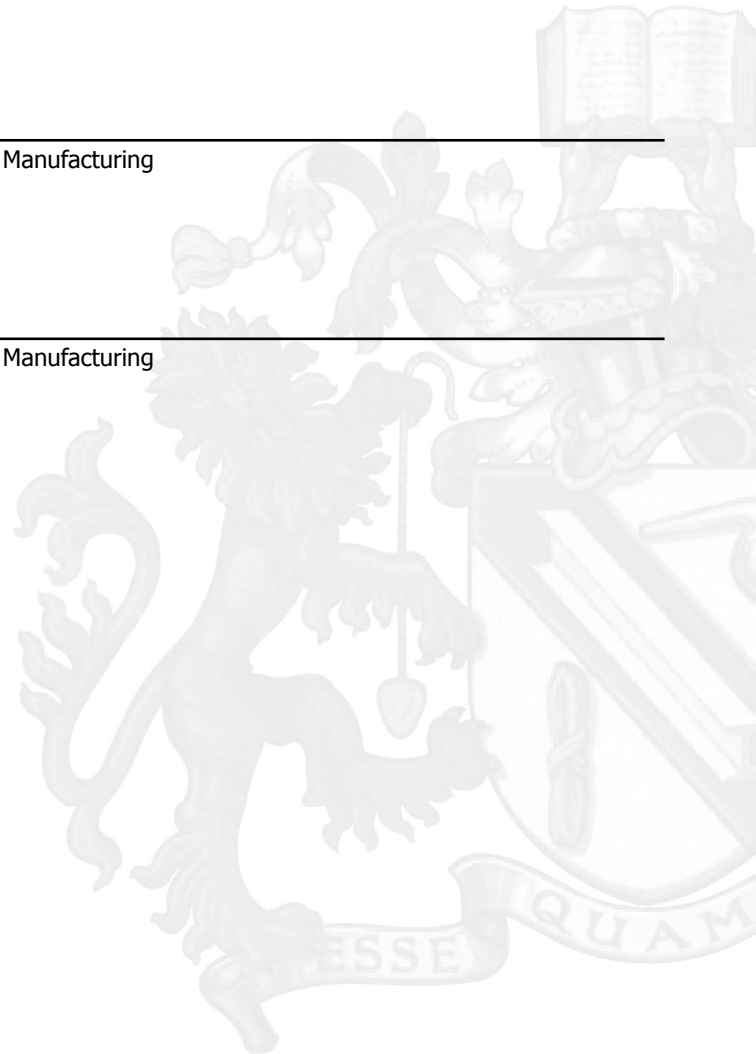
An electronic certificate can be authenticated [online](#).

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. 740 West 83rd Street Hialeah Florida 33014 USA	Manufacturing
Beckman Coulter, Inc. 700 West 83rd Street Hialeah Florida 33014 USA	Manufacturing
Beckman Coulter Inc. 7381 Empire Drive Florence Kentucky 41042 USA	Manufacturing
Beckman Coulter GmbH Europark Fichtenhain B13 47807 Krefeld Germany	Manufacturing



Original Registration Date: 2017-04-12

Latest Revision Date: 2018-03-02

Effective Date: 2018-03-19

Expiry Date: 2021-03-18

Page: 4 of 4

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.