



# NSAI

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2012

### Beckman Coulter, Inc.

250 South Kramer Blvd  
Brea  
CA 92821  
USA

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NSAI certifies that the aforementioned company has been assessed and deemed to comply with the provisions of the standard referred to above in respect of:-

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.

Approved by:  
**Kevin D. Mullaney**  
Chief Executive Officer - NSAI Inc.

Approved by:  
**Susan Murphy**  
European Medical Device Operations Manager



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Registration Number: MD19.6001  
Certification Granted: 19 March 2015  
Effective Date: 10 February 2016  
Expiry Date: 18 March 2018

*This certificate remains valid on condition that the Approved Quality Management System is maintained in an adequate and efficacious manner.*

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All valid certifications are listed on NSAI's website – [www.nsai.ie](http://www.nsai.ie). The continued validity of this certificate may be verified under "Certified Company Search"

NSAI (National Standards Authority of Ireland), 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800 E: [info@nsai.ie](mailto:info@nsai.ie) [www.nsai.ie](http://www.nsai.ie)  
NSAI Inc. 20 Trafalgar Square, Suite 603, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412 E: [info@nsaiinc.com](mailto:info@nsaiinc.com) [www.nsaiinc.com](http://www.nsaiinc.com)



# NSAI

## Annex to Certificate No. MD19.6001

### Scope of Registration:

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.

Additional facilities covered by this certificate:

#### Activity

#### Location

Headquarters (\*Diagnostics div.)  
Administration, Design and  
Development, Manufacturing  
and Remanufacture, Service  
(Technical Support Center),  
Distribution

Beckman Coulter, Inc.  
250 South Kraemer Blvd  
Brea, CA 92821  
USA  
File No.: MD19.6001

Manufacturing

Beckman Coulter, Inc.  
2470 Faraday Ave  
Carlsbad, CA 92010  
USA  
File No.: MD19.6001/B

Distribution

Beckman Coulter, Inc.  
2295 Progress Drive  
Hebron, KY 41048  
USA  
File No.: MD19.6001/D

Design and Development

Beckman Coulter, Inc.  
1000 Lake Hazeltine Drive  
Chaska, MN 55318  
USA  
File No.: MD19.6001/E

Design and Development,  
Service (Technical Support  
Center)

Beckman Coulter, Inc.  
322 Lake Hazeltine Drive  
Chaska, MN 55318  
USA  
File No.: MD19.6001/F



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### Additional facilities covered by this certificate:

Activity	Location
Distribution	Beckman Coulter, Inc. 312 Lake Hazeltine Drive Chaska, MN 55318 USA File No.: MD19.6001/G
Manufacturing, Administration	Beckman Coulter, Inc. 326 Lake Hazeltine Drive Chaska, MN 55318 USA File No.: MD19.6001/H
Manufacturing	Beckman Coulter, Inc. 316 Lake Hazeltine Drive Chaska, MN 55318 USA File No.: MD19.6001/J
Design and Development	Beckman Coulter, Inc. 36 Cherry Hill Drive Danvers, MA 01923 USA File No.: MD19.6001/L
Manufacturing	Beckman Coulter GmbH Europark Fichtenhain B13 47807 Krefeld Germany File No.: MD19.6001/M
Installation, Service	Beckman Coulter, Inc. 5355 West 76 <sup>th</sup> Street Indianapolis, IN 46268 USA File No.: MD19.6001/P



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Additional facilities covered by this certificate:

Activity	Location
Service	Beckman Coulter, Inc. 5350 Lakeview Parkway South Indianapolis, IN 46268 USA File No.: MD19.6001/Q
Administration, Design, Manufacturing, Service (Technical Support), Distribution	Beckman Coulter, Inc. 11800 SW 147 <sup>th</sup> Avenue Miami, FL 33196 USA File No.: MD19.6001/R
Distribution and Manufacturing	Beckman Coulter, Inc. 780 W. 83 <sup>rd</sup> Street Hialeah, FL 33014 USA File No.: MD19.6001/S
Manufacturing	Beckman Coulter, Inc. 740 W. 83 <sup>rd</sup> Street Hialeah, FL 33014 USA File No.: MD19.6001/T
Manufacturing	Beckman Coulter GmbH 7381 Empire Drive Florence, KY 41042 USA File No.: MD19.6001/U
Manufacturing	Beckman Coulter, Inc. 700 W. 83 <sup>rd</sup> Street Hialeah, FL 33014 USA File No.: MD19.6001/Y



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Additional facilities covered by this certificate:

#### Activity

Distribution

#### Location

Beckman Coulter, Inc  
785 Lindbergh Court  
Hebron, KY 41048  
USA  
File No.: MD19.6001/Z