

Management System Certificate

Certificate No.:
240609-2017-AQ-BRA-NA-PS Rev. 1.0

Project No.:
PRJC-187986-2009-MS-C-BRA

Initial Certification Date:
26 OCTOBER 2017

Valid Until:
26 OCTOBER 2021

This is to certify that the management system of:

BECTON DICKINSON INDUSTRIAS CIRURGICAS LTDA

Av. Pres. Juscelino Kubitscheck, 273 Francisco Bernardino /
36081-000 Juiz de Fora MG/ Brazil

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

**MANUFACTURING OF SAFETY AND CONVENTIONAL INTRAVENOUS
CATHETERS AND WING NEEDLE SETS, NEEDLES AND CANNULAS,
GLASS SYRINGES, AND ANESTHESIA TRAYS.**

Place and Date:
Høvik, 27 September 2018



For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

The undersigned Notary Public hereby certifies that Tone Kolpus has signed this document.
The signature is certified on the basis of the signature deposited in our register of signatories.
Asker og Bærum tingrett, 19 February 2019

Betty Rødsten Gilde

Notary Public
Betty Rødsten Gilde
Senior Executive Officer - 67 57 65 46



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: **Norway**
2. This public document has been signed by:
Betty Rødsten Gilde
3. Acting in the capacity of:
notary public
4. Bears the seal/stamp of:
Notarius Publicus in Asker and Bærum

CERTIFIED

5. **Oslo** 6. Date: **19.02.2019** 8. No.: **2019 - 47541**

7. **County Governor of Oslo and Viken**

9. Seal/Stamp

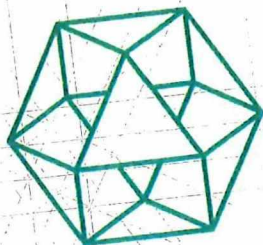
10. Signature:

Jeanette Johansen

Jeanette Johansen

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued.





NSAI

Certificate of Registration of Quality Management System to ISO 13485:2016

The National Standards Authority of Ireland certifies that:

BD Medical - Diabetes Care
1329 West Highway 6
Holdrege, NE 68949
USA

has been assessed and deemed to comply with the
requirements of the above standard in respect of the scope of
operations given below:

**The Manufacture, Packaging, Sterilization and Contract
Sterilization of Drug Delivery Devices including Syringes
and Pen Needles, Infusion Sets, Alcohol Swabs, and
Device Components for Assembly at other BD Locations.**

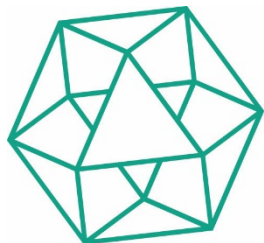
Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Registration Number: CM19.1436
Certification Granted: March 21, 1995
Effective Date: January 18, 2020
Expiry Date: January 17, 2023



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800
National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412



NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

BD Caribe Ltd.

Road 31 Km.24.3

Juncos, PR 00777-4010

Puerto Rico

has been assessed and deemed to comply with the
requirements of the above standard in respect of the scope
of operations given below:

The manufacture of sterile and non-sterile, single use devices including specialty needles (epidural, spinal, biopsy), chest drain valve, bladder drain catheter, catheter adapter and accessories, micro-collection, specimen collection, blood transfer and lancets.

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices
/ Head of Notified Body

Registration Number: MD19.1805
Certification Granted: January 16, 1995
Effective Date: February 22, 2019
Expiry Date: February 28, 2021



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800



Letter of Authenticity

This is to certify that the attached ISO 13485:2016 Quality Management System Certificate of Registration (No.FM 71665, Expiry 2021-10-28) is a true and correct copy.

Sincerely,

Kimberly Geisler
Regulatory Affairs Manager

State of Utah

§

County of Salt Lake

On this 18th day of December, in the year 2018, before me, Marie Ross, personally appeared Kimberly Geisler, proved to me through satisfactory evidence of identification, which was a Utah driver license, to be the person whose name is signed on the preceding or attached document in my presence.

Notary Signature



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Becton Dickinson Infusion
Therapy Systems Inc.
9450 South State Street
Sandy
Utah
84070
USA

Holds Certificate No:

FM 71665

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture and distribution of disposable, sterile medical devices including needles, catheter for peripheral and central vascular access and insertion procedure trays, catheter introducers, catheter adapters, catheter flush valves and connector/adaptor tubing, catheter injection ports, extension tubing, stopcocks and catheter accessories. The design, development, manufacture and distribution of surgical scrub brushes and anti-microbial solution dispensers. The manufacture of microbiological reagent droppers, culture collection and transport devices, disposable environmental chambers and syringe assemblies. On-Site EO Sterilization, including contract sterilization, for medical devices. The design, development, manufacture and distribution of sterile cannula products.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-12-17

Latest Revision Date: 2018-12-15

Effective Date: 2019-01-01

Expiry Date: 2021-10-28

Page: 1 of 2



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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
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: **FM 71665**

Location

Registered Activities

Carefusion 303, Inc.
10020 Pacific Mesa Blvd.
San Diego
California
92121
USA

The design and development of disposable, sterile medical devices including connector/adaptor tubing, catheter injection ports, extension tubing, stopcocks and catheter accessories.

Becton Dickinson Infusion
Therapy Systems Inc.
9450 South State Street
Sandy
Utah
84070
USA

The design, development, manufacture and distribution of disposable, sterile medical devices including needles, catheter for peripheral and central vascular access and insertion procedure trays, catheter introducers, catheter adapters, catheter flush valves and connector/adaptor tubing, catheter injection ports, extension tubing, stopcocks and catheter accessories. The design, development, manufacture and distribution of surgical scrub brushes and anti-microbial solution dispensers. The manufacture of microbiological reagent droppers, culture collection and transport devices, disposable environmental chambers and syringe assemblies. On-Site EO Sterilization, including contract sterilization, for medical devices. The design, development, manufacture and distribution of sterile cannula products.

Original Registration Date: 2002-12-17

Effective Date: 2019-01-01

Latest Revision Date: 2018-12-15

Expiry Date: 2021-10-28

Page: 2 of 2

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
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.



OFFICE OF THE LIEUTENANT GOVERNOR

Apostille

(*Convention de La Haye du 5 octobre 1961*)

1. Country: United States of America
2. This public document has been signed by MARIE ROSS
3. Acting in the capacity of NOTARY PUBLIC, STATE OF UTAH
4. Bears the seal/stamp of MARIE ROSS, NOTARY PUBLIC, STATE OF UTAH

Certified

5. at Salt Lake City, Utah, U.S.A.
6. the 27th day of December, 2018
7. by Spencer J. Cox, Lieutenant Governor, State of Utah, U.S.A.
8. Number: 351008
9. Seal/Stamp:

10. Signature



Spencer J. Cox
Lieutenant Governor

This certification attests only to the authenticity of the signature of the official who signed the affixed document, the capacity in which that official acted, where appropriate the identity of the seal or stamp which the document bears. This certification is not intended to imply that the contents of the document are correct, nor that they have the approval of the State of Utah.

Management System Certificate

Certificate No.:
240136-2017-AQ-BRA-NA-PS Rev. 1.0

Project No.:
PRJC-252535-2010-MSL-BRA

Initial Certification Date:
26 MAY 1998

Valid Until:
12 October 2020

This is to certify that the management system of:

BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA

Rua Cyro Correia Pereira 550, Curitiba, 81170-230, Brazil

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

MANUFACTURE, PACKING, REPACKING, STERILIZATION, STORAGE THE STERILE HYPODERMIC NEEDLES OF SINGLE USE, SHARP COLLECTORS, ORAL SYRINGES, STERILE HYPODERMIC PLASTIC SYRINGES OF SINGLE USE AND STERILE HYPODERMIC SYRINGES WITH REUSE PREVENTION FEATURE WITH OR WITHOUT SAFETY SHIELDS.

Place and Date:
Høvik, 2 January 2019



For:
DNV GL PRESAFE AS



Eugenie Winger Husebye

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Becton, Dickinson and Company
Pottery Road
Dun Laoghaire
Co. Dublin
Ireland

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

**The Manufacture, Packaging and Sterilization of Insulin
Delivery Systems**

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Caroline Dore Geraghty
Director of Medical Devices/Head of Notified Body

Certificate Number: MD19.1385
Certification Granted: 21 March 1995
Effective Date: 01 April 2020
Expiry Date: 31 March 2023



*All valid certifications are listed on NSAI's website – 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 www.nsai.ie
NSAI Inc. 20 Trafalgar Square, Suite 603, Nashua, New Hampshire, USA T +1 603 882 4412 E: info@nsaiinc.com www.nsaiinc.com

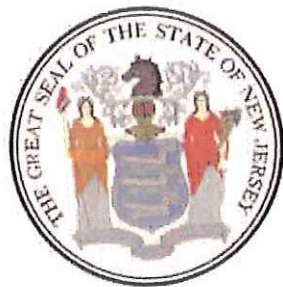
APOSTILLE

(CONVENTION DE LA HAYE DU 5 OCTOBRE 1961)

1. COUNTRY: UNITED STATES OF AMERICA
2. THIS PUBLIC DOCUMENT HAS BEEN SIGNED BY:
PASQUALE AMATO
3. ACTING IN THE CAPACITY OF:
NOTARY PUBLIC OF NEW JERSEY
4. BEARS THE SEAL/STAMP OF:
PASQUALE AMATO, NOTARY

CERTIFIED

5. AT TRENTON, NEW JERSEY
6. THE 30TH DAY OF APRIL 2019
7. BY: Elizabeth Maher Muoio
State Treasurer
8. NO: A681803
9. SEAL/STAMP:
10. SIGNATURE



A handwritten signature in black ink, appearing to read "Elizabeth Maher Muoio".

Elizabeth Maher Muoio
State Treasurer

Certificate Number: 141361985

Verify this certificate at
https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

1 Becton Drive
Franklin Lakes, NJ 07417
www.bd.com



April 23, 2019

To Whom It May Concern,

This is to certify that the attached is a true and original copy.

A handwritten signature in dark ink, appearing to read "Pamela Sanecki", is written over a horizontal line.

Pamela Sanecki
Regulatory Affairs Coordinator
Becton, Dickinson and Company (BD)

SWORN TO AND SUBSCRIBED BEFORE ME
THIS 23 DAY OF Apr 2019

A handwritten signature in dark ink, appearing to read "P. Amato", is written above a rectangular notary stamp.

Pasquale Amato
Notary Public
New Jersey
My Commission Expires 5-19-2023
No. 2373789





Certificate of Registration

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

This is to certify that:

Becton, Dickinson and Company
Belliver Industrial Estate
Belliver Way
Roborough
Plymouth
PL6 7BP
United Kingdom

Holds Certificate Number:

MD 613320

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture of sterile blood collection tubes, urine tubes, urine specimen receptacles, syringes, blood collection needles, wingsets and lancets, non-sterile needle holders and supply and outsourced servicing of in vitro diagnostic instruments used in the determination of ESR for professional use.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-03-31

Latest Revision Date: 2019-02-26

Effective Date: 2019-03-01

Expiry Date: 2022-01-07

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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](http://www.bsigroup.com/ClientDirectory).
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.