

**BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS  
LTDA**

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

2020-05-27

**Subject: COVID-19 – Postponement of the recertification audit  
Management System Certification according to ISO 13485:2016 standard**

Dear Customer,

As part of the COVID-19 contingency and with the aim of ensuring the safety of employees/collaborators for the benefit of the entire community of customers and stakeholders and at the same time the continuity of activities, DNV GL is committed to address the critical issues in carrying out certification verification activities, in accordance with the general and specific accreditation requirements.

For these reasons and as agreed by the Operation and Technical functions of DNV GL (with reference to the general requirements based on IAF ID 3 "Information document for the management of extraordinary events or circumstances affecting ABs, CABs and certified organizations" (chapter 4.1)), we inform you that your recertification audit will be carried out or completed within 6 months of the expiration of the current certificate, no. 240136-2017-AQ-BRA-NA-PS Rev. 1.0. The validity of the aforementioned certificate is considered extended for a maximum period of 6 months and will be renewed, as usual, upon the positive outcome of the technical audit review and certification decision by DNV GL management.

Thanks for the collaboration, we remain available for any further clarification.

Sincerely,

For DNV GL Presafe AS

Björg Synnøve Nesgård  
Operations Manager Medical, Certification Manager ISO 13485

# 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](http://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.

# 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](http://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

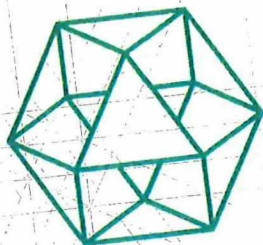
10. Signature:

*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



## 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:

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**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

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



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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 18<sup>th</sup> 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](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: **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.  
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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.



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.



# 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:

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**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

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



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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, USA T +1 603 882 4412 E: [info@nsaiinc.com](mailto:info@nsaiinc.com) [www.nsaiinc.com](http://www.nsaiinc.com)

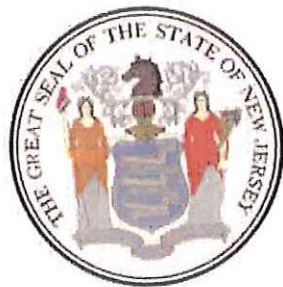
*APOSTILLE*

*(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](https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp)



1 Becton Drive  
Franklin Lakes, NJ 07417  
[www.bd.com](http://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

Page: 1 of 1



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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](https://www.bsigroup.com/ClientDirectory).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://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.