



Commonwealth of Virginia
The Honorable Kay Coles James - Secretary of the Commonwealth
Document revised January 24, 2022

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: **United States of America**
Pays / País:
- This public document
Le présent acte public / El presente documento público
2. has been signed by **Sami A. Swadek**
a été signé par
ha sido firmado por
3. acting in the capacity of **Notary Public**
agissant en qualité de
quien actúa en calidad de
4. bears the seal / stamp of **Sami A. Swadek - Commonwealth of Virginia**
est revêtu du sceau / timbre de
y está revestido del sello / timbre de

Certified
Attesté / Certificado

5. at **Richmond, VA**
à / en
6. the **1st day of April 2022**
le / el día
7. by **The Secretary of the Commonwealth**
par / por
8. N° **2974377-8**
sous n°
bajo el número
9. Seal / stamp:
Sceau / timbre :
Sello / timbre:
10. Signature:
Signature :
Firma:



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.

This Apostille is not valid for use anywhere within the United States of America or its territories.

Cette Apostille atteste uniquement la véracité de la signature, la qualité en laquelle le signataire de l'acte a agi et, le cas échéant, l'identité du sceau ou timbre dont cet acte public est revêtu.

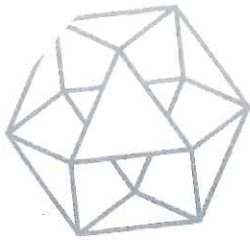
Cette Apostille ne certifie pas le contenu de l'acte pour lequel elle a été émise.

L'utilisation de cette Apostille n'est pas valable aux États-Unis d'Amérique ou dans ses territoires.

Esta Apostilla certifica únicamente la autenticidad de la firma, la calidad en que el signatario del documento haya actuado y, en su caso, la identidad del sello o timbre del que el documento público esté revestido.

Esta Apostilla no certifica el contenido del documento para el cual se expidió.

No es válido el uso de esta Apostilla en Estados Unidos de America y sus territorios



NSAI

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

Australia-Therapeutic Goods (Medical Devices) Regulations, 2002,

☒ Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure.

Brazil- RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009

Canada- Medical Devices Regulations – Part 1- SOR 98/282

Japan- MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (, as applicable)

United States- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

☒ 21 CFR 820 – Quality System Regulation

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Becton, Dickinson and Company (BD)

1 Becton Drive

Franklin Lakes, NJ 07417-1885

USA

Facility ID: F001572

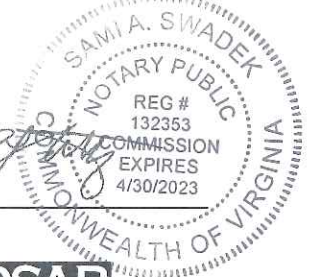
has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

**The Design and Development, Manufacture, and Distribution of
Preanalytical Products including Sterile and Non-Sterile Blood/Urine
Collection Devices, Sterile Cell Preparation Devices, Anaerobic
Specimen Collection Devices, Venting Unit Sub-Assemblies, Blood
Collection Needles, Administration Sets, Microcollection Devices and
Lancets.**

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Certificate Number: MP19.2137/Rev 1
Certification Granted: 2019/01/31
Effective Date: 2022/01/31
Expiry Date: 2025/01/30



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
All valid certifications are listed on NSAI's website – www.nsa-inc.com
The continued validity of this certificate may be verified under "Approved Client Listing"

180931 8/12



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
240136-2017-AQ-BRA-NA-PS

Initial certification date:
26 May 1998

Valid:
06 September 2021 – 12 October 2023

This is to certify that the management system of
BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA

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

and the site(s) as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

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

Place and date:
Høvik, 06 September 2021



For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp
Management Representative

Lack of fulfillment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

The undersigned Notary Public hereby certifies that Mariann Jeremiassen has signed this document.
The signature is certified on the basis of the signature deposited in our register of signatories.
Ringerike, Asker og Bærum tingrett, 10 November 2021

Ann-Cathrin Antonsen

Notary Public
Ann-Cathrin Antonsen



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: **Norway**
2. This public document has been signed by:
Ann-Cathrin Antonsen
3. Acting in the capacity of:
notary public
4. Bears the seal/stamp of:
Notary Public in Ringerike, Asker and Bærum

CERTIFIED

5. **Oslo** 6. Date: **12.11.2021** 8. No.: **2021 - 115049**

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

9. Seal/Stamp

10. Signature:

Sara Stakkeland Torstad

Sara Stakkeland Torstad

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.



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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-03-31

Latest Revision Date: 2022-01-05

Effective Date: 2022-01-08

Expiry Date: 2025-01-07

Page: 1 of 1



...making excellence a habit.™