Becton Dickinson S.A.
Camino de Valdeoliva, s/n
28750 – San Agustín del Guadalix
Madrid, Spain
Phone / *Tlf.*: +34 918 488 100
Fax: +34 918 488 101

EC DECLARATION OF CONFORMITY
DECLARACIÓN DE CONFORMIDAD CE

Manufacturer: *Fabricante:*	Becton Dickinson S.A. Camino de Valdeoliva, s/n 28750 – San Agustín del Guadalix, MADRID – ESPAÑA
Manufacturing Site(s): *Planta(s) de Fabricación:*	Becton Dickinson S.A. Camino de Valdeoliva, s/n 28750 – San Agustín del Guadalix, MADRID – ESPAÑA
Sterilization Site(s): *Planta(s) de Esterilización:*	Becton Dickinson S.A. Ctra. Mequinenza, s/n 22520 – Fraga, HUESCA – ESPAÑA
Products: *Productos:*	BD Plastipak™ Syringes *Jeringas BD Plastipak™* See attached list of references / *ver listado de referencias adjunto.*
Classification: *Clasificación:*	Class I, sterile, with measuring function, as per Rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC (June 14th, 1993). *Clase I, estéril, con función de medición, según la Regla 2 del Anexo IX de la Directiva de Productos Sanitarios 93/42/CEE (14 de junio de 1993).*
Conformity Assessment Route: *Procedimiento de evaluación de la conformidad:*	Annexes V and VII *Anexos V y VII*
GMDN:	GMDN Code / Código: 47017 / 35904 GMDN Term / Término: 47017 General-purpose syringe GMDN Term / Término: 35904 Metered-delivery hypodermic syringe

We hereby declare that the products mentioned above meet the provisions of the Council Directive 93/42/EEC of June 14th, 1993 concerning medical devices. This declaration of conformity is issued under the sole responsibility of the manufacturer. All supporting documentation is retained at the premises of the manufacturer.
Por la presente declaramos que los productos antes mencionados cumplen las disposiciones de la Directiva 93/42/EEC de 14 de junio de 1993 sobre productos sanitarios. La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante. Toda la documentación de soporte se guarda en las instalaciones del fabricante.

List of Harmonized Standards: *Lista de Normas Armonizadas:*	EN 556-1:2024, EN 1707:1996, EN ISO 10993 Series, EN ISO 11737-2:2020, EN ISO 13485:2016/A11:2021, EN ISO 15223-1:2021
Non-Harmonized standards: *Normas No Armonizadas:*	EN ISO 7886-1:2018, EN ISO 8537:2016, EN ISO 14971:2019, EN ISO 10993-10:2023, EN ISO 11135:2014/A1:2019, EN ISO 20417:2021, EN ISO 11138-2:2017, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018/A1:2021
Notified Body: *Organismo Notificado:*	Agencia Española de Medicamentos y Productos Sanitarios Parque Empresarial Las Mercedes. Edificio 8 Calle Campezo, 1 28022 – MADRID Notified Body Number / *Número del Organismo Notificado:* 0318
EC Certificate Number: *Número certificado CE:*	2000 06 0273 CP
Date of issuance of the original EC Certificate: *Inicio de la marca CE:*	Initial Date: June 19th, 1995 *Fecha inicial: 19 de junio de 1995*

Date / *Fecha:* February 24, 2025 / *24 de febrero de 2025*

Elena Morollón
Regulatory Affairs Sr. Manager
Becton Dickinson S.A.

Signature / Firma: DocuSigned by: 4181A2DF25574CC...

Becton Dickinson S.A.
Camino de Valdeoliva, s/n
28750 – San Agustín del Guadalix
Madrid, Spain
Phone / *Tlf.*: +34 918 488 100
Fax: +34 918 488 101

PRODUCT LIST
LISTA DE PRODUCTOS

THREE-PIECE STERILE BD PLASTIPAK™ SYRINGES WITHOUT NEEDLE
JERINGAS ESTÉRILES DE TRES PIEZAS SIN AGUJA BD PLASTIPAK™

Reference *Referencia*	**Description** *Descripción*	
300613	BD Plastipak™ Syringe *Jeringa BD Plastipak™*	20 mL
300866	BD Plastipak™ Syringe *Jeringa BD Plastipak™*	50 mL
301183	BD Plastipak™ Syringe *Jeringa BD Plastipak™*	20 mL
301231	BD Plastipak™ Syringe *Jeringa BD Plastipak™*	30 mL
303172	BD Plastipak™ Syringe *Jeringa BD Plastipak™*	1 mL

THREE-PIECE STERILE BD PLASTIPAK LUER-SLIP INSULIN SYRINGES
JERINGAS BD PLASTIPAK CONO LUER PARA INSULINA

Reference *Referencia*	**Description** *Descripción*	
303173	BD Plastipak™ U-40 Syringe *Jeringa BD Plastipak™ U-40*	1 mL
303174	BD Plastipak™ U-100 Syringe *Jeringa BD Plastipak™ U-100*	1 mL

THREE-PIECE STERILE BD PLASTIPAK SYRINGES WITH CATHETER TIP CONNECTION
JERINGAS BD PLASTIPAK CON CONEXIÓN CONO CATÉTER

Reference *Referencia*	**Description** *Descripción*	
300605	BD Plastipak™ Syringe *Jeringa BD Plastipak™*	100 mL
300867	BD Plastipak™ Syringe *Jeringa BD Plastipak™*	50 mL

Under Art. 120 (3) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 amended by Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 the responsibility of surveillance of certificate 2000 06 0273 CP has been transferred to BSI (2797) which has issued certificate AR120 818302 on January 10, 2025.

Date */ Fecha:* February 24, 2025 */ 24 de febrero de 2025*

Elena Morollón
Regulatory Affairs Sr. Manager
Becton Dickinson S.A.

Signature / Firma: DocuSigned by: 4181A2DF25574CC...

30 Tuas Ave 2
Singapore 639461

bd.com

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Becton Dickinson Medical (S) Pte Ltd
Manufacturer address and contact details	30 Tuas Avenue 2, Singapore 639461
Single Registration Number (SRN) (if available)	SG-MF-000023991

Authorised Representative name (if applicable)	Becton Dickinson Distribution Center NV
Authorised Representative address and contact details	Laagstraat 57 B-9140 Teems Belgium
Single Registration Number (SRN) (if available)	N.A (AR is Becton Dickinson Ireland Ltd for MDR)

Notified body name (if applicable)	☑ See attached schedule
Notified body number (if applicable)	☑ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☑ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☑ See attached schedule
End date of extended validity/transition period	☑ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

30 Tuas Ave 2
Singapore 639461

bd.com

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  - ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  - ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  - ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  - ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  - ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

  ☑ Expired/expires *after* 20 March 2023:

  Choose one applicable statement:

  - ☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  - ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

30 Tuas Ave 2
Singapore 639461

bd.com

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☑ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Becton Dickinson Medical (S) Pte Ltd
30 Tuas Avenue 2, Singapore 639461
08 April 2024

Chiang Meng Chee
Senior Regulatory Affairs Executive
Contact: meng_chee_chiang@bd.com

30 Tuas Ave 2
Singapore 639461

bd.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
301320	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302100	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302101	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302104	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302106	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302109	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302110	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302113	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302118	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302130	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302135	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302143	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302145	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302146	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302149	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
303063	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
303064	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
303131	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
303132	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
303133	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
301995	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302799	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302802	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302800	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302801	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

30 Tuas Ave 2
Singapore 639461

bd.com

301991	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
301801	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
301805	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
301807	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
301808	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302006	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302804	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302805	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	No
302153	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
302171	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
302172	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
302173	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
302204	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
303061	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
303062	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
302015	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
302017	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
302032	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
301988	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
303283	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
303284	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
300841	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
302119	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
300204	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes
302011	CE 01487	26-May-2024	BSI - 2797	BSI - 2797	31-Dec-2028	Yes

Becton Dickinson Medical (S) Pte Ltd.

30 Tuas Avenue 2

639461

Singapore

November 6, 2023

Notified Body Confirmation Letter

Reference: EU2023-607/674374

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Becton Dickinson Medical (S) Pte Ltd.
30 Tuas Avenue 2
639461
Singapore
SRN Number (if available): SG-MF-000023991

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive

93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Luis Martinez

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BD Syringe with PrecisionGlide™ Needle	Class IIa	N/A	CE 01487; NB# 2797
BD Syringe without PrecisionGlide™ Needle	Class IIa	N/A	CE 01487; NB# 2797
BD Syringe Bulk Non-Sterile	Class IIa	N/A	CE 01487; NB# 2797
BD PrecisionGlide™ Needle	Class IIa	N/A	CE 01487; NB# 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/11/06	Initial issue

BD Medical (S) Pte Ltd
30 Tuas Ave 2
Singapore 639461

bd.com

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461 Singapore
Authorised Representative:	Becton Dickinson Distribution Center NV Laagstraat 57, B-9140 Temse, Belgium
Manufacturing Site(s):	Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461 Singapore
Products:	Refer to Appendix
Classification:	Syringes with Needles Class IIa, Annex IX, Rule 6 Syringes without Needles (Sterile) Class Is/m, Annex IX, Rule 1 Syringes without Needles (Non-Sterile) Class Im, Annex IX, Rule 1
Conformity Assessment Route:	Annex V, Annex VII
GMDN:	**GMDN Code:** 35904 **GMDN Term:** Injection Syringe, Single Use **Definition:** A device used to inject/infuse or withdraw fluids or gas. It is typically constructed of glass or plastic and consists of a barrel with measurement lines and a plunger. It is most commonly used for the administration of medications or for blood sampling.

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer.

Advancing the world of health

BD Medical (S) Pte Ltd
30 Tuas Ave 2
Singapore 639461

bd.com

EC DECLARATION OF CONFORMITY

Harmonised Standards:	EN ISO 14971:2012 EN ISO 13485:2016 EN ISO 10993-1:2020 EN ISO 11607-1:2006/Amd.1:2014 EN ISO 11607-2:2006/Amd.1:2014 EN ISO 11135-1::2014/Amd 1.2019 EN ISO 11137-1:2015/A2:2019 EN ISO 11737-1:2018/Amd. 1:2021 EN ISO 11137-2:2013/Amd.1:2022 EN 1041:2008 EN ISO 15223-1:2016
Non-Harmonised Standards:	ANSI/AQS Z1.4: 2013 ISO 594-1:1986 (with the exception of section 4.4 and 5.4) ISO 594-2:1998 ISO 6009:2016 ISO 7864:1993 ISO 7886-1:1993/COR 1:1995 ISO 7886-2:1996
Notified Body:	**Notified Body Name**: BSI **Notified Body Address**: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands **Notified Body Number**: 2797
CE Certificate Number:	CE 01487
Date of issuance of original CE certificate:	11 December 1996

Date: 26 Sep 2023

Loo Mooi Leng
QA Manager
Becton Dickinson Medical (S) Pte Ltd

Advancing the world of health

BD Medical (S) Pte Ltd
30 Tuas Ave 2
Singapore 639461

bd.com

EC DECLARATION OF CONFORMITY

Product Listing

A) ETO sterile unit pack. ETO compatible.

Catalogue Number	Product Description
300141	20ml Precise Syringe Luer-Lok™ Tip
300841	Syringe 1ml LS 25GA 5/8IN CHIN Graphics (0.5 x 16)
301320	1ml Syringe Slip Tip with BD PrecisionGlide™ Needle 25G 5/8 TW (0.5mm x 16mm)
302100	1ml Tuberculin Syringe Slip Tip
302101	1ml Syringe Slip Tip with BD PrecisionGlide™ 27G 1/2 (0.4mm x 13mm)
302104	1ml Syringe Slip Tip with BD PrecisionGlide™ Needle 25G 5/8 TW (0.5mm x 16mm)
303284	1ml Syringe Slip Tip with BD PrecisionGlide™ Needle 27G 1/2 (0.4mm x 13mm)
302106	3ml Syringe Slip Tip
302109	3ml Syringe Slip Tip with BD PrecisionGlide™ Needle 24G 1 TW (0.55mm x 25mm)
302110	3ml Syringe Slip Tip with BD PrecisionGlide™ Needle 23G 1 TW (0.6mm x 25mm)
302113	3ml Syringe Luer-Lok™ Tip
302118	3ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 23G 1 TW (0.6mm x 25mm)
302119	3ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 23G 1 1/4 TW (0.6mm x 32mm)
302130	5ml Syringe Slip Tip
301988	5ml Syringe Slip Tip with BD PrecisionGlide™ Needle 23G 1 TW (0.6mm x 25mm)
302135	5ml Syringe Luer-Lok™ Tip
302143	10ml Syringe Slip Tip
302145	10ml Syringe Slip Tip with BD PrecisionGlide™ Needle 21G 1 1/2 TW (0.8mm x 38mm)
302146	10ml Syringe Eccentric Tip
302149	10ml Syringe Luer-Lok™ Tip

BD Medical (S) Pte Ltd
30 Tuas Ave 2
Singapore 639461

bd.com

EC DECLARATION OF CONFORMITY

Catalogue Number	Product Description
302153	10ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 21G 1 1/2 TW (0.8m x 38mm)
302171	10ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 21G 1 TW (0.8mm x 25mm)
302172	5ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 21G 1 1/2 TW (0.8mm x 38mm)
302173	5ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 23G 1 TW (0.6mm x 25mm)
302204	2ml Syringe Slip Tip
302810	5ml Syringe Luer-Lok™ Tip with Coloured Plunger
303061	3ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 24G 1 TW (0.55mm x 25mm)
303062	3ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 23G 1 TW (0.6mm x 25mm)
303063	5ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 23G 1 TW (0.6mm x 25mm)
303064	10ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 21G 1 TW (0.8mm x 25mm)
303065	20ml Precise Syringe Luer-Lok™ Tip
303131	3ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 23G 1 TW (0.6mm x 25mm)
303132	5ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 23G 1 TW (0.6mm x 25mm)
303133	10ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 21G 1 1/2 TW (0.8m x 38mm)
305482	5ml Syringe Slip Tip
307808	10ml Syringe Slip Tip with BD PrecisionGlide™ Needle 23G x 1 TW (0.6mm x 25mm)

B) **Non-sterile bulk pack**, ETO compatible.

Catalogue Number	Product Description
301995	Syringe 3ml Luer-Lok Bulk Non-Sterile
302799	Syringe 3ml Luer-Lok Bulk Non-Sterile
302802	Syringe 10ml Luer –Lok Bulk Non-Sterile

Document: TF000002-DEC (SG)
Valid From: 29-Sep-2023 To: 31-Dec-9999
Print Date: 12-Oct-2023 00:12:20 GMT Daylight Time
Doc Type: ZRF
Doc Part: EN
Usage: Production Usage
Status: Released EFFECTIVE
Revision: N/A
Version: O
Change #: N/A
Classification: Restricted

BD Medical (S) Pte Ltd
30 Tuas Ave 2
Singapore 639461

bd.com

EC DECLARATION OF CONFORMITY

C) **Non-sterile bulk pack**, ETO compatible.

Catalogue Number	Product Description
302800	Syringe 5ml Luer-Lok Bulk Non-Sterile
302801	Syringe 5ml Luer Slip Bulk Non-Sterile
305958	Syringe 10ml Luer Slip Bulk
301991	Syringe 10ml Luer –Lok Bulk Non-Sterile

BD Medical (S) Pte Ltd
30 Tuas Ave 2
Singapore 639461

bd.com

REVISION RECORD PAGE

REVISION RECORD			
REVISION NUMBER	**REVISION DESCRIPTION**	**ECO NUMBER**	**PREPARED BY**
19	Removed following catalogue numbers: 300140, 300142, 301304, 301321, 302111, 302117, 302131, 302137, 302147, 302170, 302236, 303060, 301993, 301994, 301996, 301992, 300143, 300144, 303066, 300145 (ECO 500000324795, ACR PCC-2021-00154) 300771, 301311, 301989, 302133, 302151, 307800, 307803, 307806, 307807, 307809, 307811, 30210155, 30211955, 30213955, 30215355 (ECO 500000307554, ACR PCC-2021-00154)	NA	Chiang Meng Chee
18	Removed the table "E) Non-sterile bulk pack, Gamma compatible" and the catalogue number 305462 in this table. (ECO 500000256079, ACR PCC-2021-00281)	NA	Chiang Meng Chee
17	Added EN ISO 11137-2:2013/Amd.1:2022 in Harmonised Standards.	NA	Chiang Meng Chee

Document: TF000002-DEC (SG)
Valid From: 29-Sep-2023 To: 31-Dec-9999
Print Date: 12-Oct-2023 00:12:20 GMT Daylight Time
Doc Type: ZRF
Doc Part: EN
Usage: Production Usage
Status: Released EFFECTIVE
Revision: N/A
Version: O
Change #: N/A
Classification: Restricted

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

CERTIFICADO CE
de acuerdo con los Anexos VII punto 5 y V punto 3 de la Directiva 93/42/CEE
EC CERTIFICATE
in accordance with Annexes VII section 5 and V section 3 of Directive 93/42/EEC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
2000 06 0273 CP	**Desde/*From***	**25-05-2020**	**Hasta/*To***	**24-05-2024**	**0318**

A favor de/*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name*: **BECTON DICKINSON S.A.**
Dirección/*Address*: **Camino de Valdeoliva, s/n. 28750- SAN AGUSTÍN DEL GUADALIX (Madrid), España**
Representante autorizado ante la UE / *Authorized EU representative*: Idem

Para el producto estéril con función de medición / *For the sterile product with a measuring function*

Categoría/*Category*: **Productos de un solo uso / *Single-use products***
Grupo genérico/ *Generic group*: **Productos para inyección y/o aspiración de fluidos / *Instruments for injection and/or aspiration of fluids***
Tipo/*Type*: Especificado en Anexos de este Certificado/*Specified in Annexes to this Certificate*

Elaborado en/*In the facilities*:

Camino de Valdeoliva, s/n. 28750- SAN AGUSTÍN DEL GUADALIX (Madrid). España

Fecha inicial / *Initial date:* 19-06-1995
Fecha de prórroga anterior / *Previous extension date:* 25-05-2015

Este certificado se emite en base a la auditoría contenida en el expediente nº 95 04 0005, y garantiza que los aspectos de fabricación relacionados con la obtención y el mantenimiento de las condiciones de esterilidad y con la conformidad de los requisitos metrológicos han sido evaluados de acuerdo con el punto 3 del Anexo V de la Directiva. / *This certificate is issued on the basis of the audit contained in dossier no 95 04 0005, and guarantees that the aspects of manufacture concerned with securing and maintaining sterile conditions and with the conformity with the metrological requirements have been assessed in accordance with Annex V section 3 of Directive.*

Madrid, 22 de mayo de 2020
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 22/05/2020
Puede comprobar la autenticidad del documento en la sede de la AEMPS: https://sede.aemps.gob.es
Localizador: P D 3 K C 7 L D 3 5

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE
de acuerdo con los Anexos VII punto 5 y V punto 3 de la Directiva 93/42/CEE

EC CERTIFICATE
in accordance with Annexes VII section 5 and V section 3 of Directive 93/42/EEC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
2000 06 0273 CP	**Desde/*From***	**25-05-2020**	**Hasta/*To***	**24-05-2024**	**0318**

A favor de/*In favor of*:

Fabricante/*Manufacturer*:
Nombre/*Name*: **BECTON DICKINSON S.A.**
Dirección/*Address*: **Camino de Valdeoliva, s/n. 28750- SAN AGUSTÍN DEL GUADALIX (Madrid), España**
Representante autorizado ante la UE / *Authorized EU representative*: Idem

Tipo de producto / *Device type*: Jeringas sin aguja, Jeringas para insulina / *Syringes without needle, Insulin syringes*

Clasificación / *Classification:* I estéril con función de medición / *I sterile with a measuring function*

1. **Jeringas estériles de tres piezas sin aguja BD Plastipak™ / *Three-piece sterile BD Plastipak™ syringes without needle***

   Códigos NANDO / *NANDO codes*: MD 0104, MDS 7006

   1.1. Jeringas cono Luer / *Luer-Slip syringes*

   1.1.a). Jeringas de: / *Syringes of:* 1 ml

   1.1.b). Jeringas de: / *Syringes of:* 2 ml

   1.1.c). Jeringas de: / *Syringes of:* 5 ml

   1.1.d). Jeringas de: / *Syringes of:* 10 ml

   1.1.e). Jeringas de: / *Syringes of:* 20 ml

   1.1.f). Jeringas de: / *Syringes of:* 30 ml

   1.1.g). Jeringas de: / *Syringes of:* 50 ml

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE
de acuerdo con los Anexos VII punto 5 y V punto 3 de la Directiva 93/42/CEE

EC CERTIFICATE
in accordance with Annexes VII section 5 and V section 3 of Directive 93/42/EEC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
2000 06 0273 CP	**Desde/*From***	**25-05-2020**	**Hasta/*To***	**24-05-2024**	**0318**

1.2. Jeringas cono Luer para insulina / *Luer-Slip insulin syringes*

1.2.a). Jeringas para insulina de 1 ml 40 UI / *Insulin 1ml 40 I.U. syringes*

1.2.b). Jeringas para insulina de 1 ml 100 UI / *Insulin 1ml 100 I.U. syringes*

1.3. Jeringas con conexión Cono Catéter / *Syringes with Catheter Tip connection*

1.3.a). Jeringas de: / *Syringes of:* 50 ml

1.3.b). Jeringas de: / *Syringes of:* 100 ml

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración CE de conformidad. *This certificate covers all trademarks of these products included by the manufacturer in his EC declaration of conformity.*

Madrid, 22 de mayo de 2020
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318

By Royal Charter

Supplementary information to AR120 818302

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

BECTON DICKINSON S.A.
Camino de Valdeoliva, s/n. 28750- SAN AGUSTÍN DEL GUADALIX (Madrid), España

Date: 10 January 2025

Changes Approved:

Date	Reference Number	Action
10 January 2025	30288755	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of BD Plastipak™ Catheter Tip Syringe, BD Plastipak™ Luer-Slip Tip Syringe (without needle), BD Plastipak™ Luer-Slip insulin syringe (without needle). Original NB Certificate Number: 2000 06 0273 CP

Inspiring trust for a more resilient world.

10 January 2025

Becton Dickinson, S.A.
Camino de Valdeoliva, s/n
San Agustin del Guadalix Madrid
28750
Spain

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
2000 06 0273 CP	AR120 818302	93/42/EEC Annex V	30288755	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of BD Plastipak™ Catheter Tip Syringe, BD Plastipak™ Luer-Slip Tip Syringe (without needle), BD Plastipak™ Luer-Slip insulin syringe (without needle). Original NB Certificate Number: 2000 06 0273 CP

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl