Becton Dickinson S.A.
Camino de Valdeoliva, s/n
28750 – San Agustín del Guadalix
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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 S.A.
Manufacturer address and contact details	Camino de Valdeoliva, s/n San Agustín del Guadalix (Madrid), 28750, Spain Tel.: +34 91 848 81 00 Email: Elena.Morollon@bd.com
Single Registration Number (SRN) (if available)	Not available

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

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

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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.

  X Expired/expires *after* 20 March 2023:

  Choose one applicable statement:

  X 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.

[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

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☐ 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.

➢ **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.

X 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:

Full Company Name: **Becton Dickinson S.A.**

Location & Date **San Agustín del Guadalix / 19-Jan-2024**

Signature, Print Name, Title:

DocuSigned by:
Elena Morollón
4181A2DF25574CC...

Elena Morollón, Regulatory Affairs Manager

Contact Details (at least email): Elena.Morollon@bd.com

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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)
400978 - BD® Whitacre Spinal NRFit™ Needle 22 G x 3 1/2" (0.70 x 88.9 mm)	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400979 - BD® Whitacre Spinal NRFit™ Needle 24 G x 3 1/2" (0.55 x 88.9 mm	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400980 - BD® Whitacre Spinal NRFit™ Needle 25 G x 3 1/2" (0.50 x 88.9 mm)	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400220 - BD® Whitacre Spinal NRFit™ Needle 25 G x 4 1/16" (0.50 x 103.2 mm)	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400221 - BD® Whitacre Spinal NRFit™ Needle 25 G	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*

[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)

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x 4 11/16" (0.50 x 119.1 mm)						
400222 - BD® Whitacre Spinal NRFit™ Needle 27 G x 4 1/16" (0.40 x 103.2 mm)	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400223 - BD® Whitacre Spinal NRFit™ Needle 27 G x 4 11/16" (0.40 x 119.1 mm)	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400982 - BD® Whitacre Spinal NRFit™ Needle 27 G x 3 1/2" (0.40 x 88.9 mm)	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400227 - BD® Whitacre Spinal NRFit™ Needle 27 G x 3 1/2" (0.40 x 88.9 mm) + BD® Spinal Introducer NRFit™ Needle 22 G x 1.25" (0.70 × 31.8 mm)	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400228 - BD® Whitacre Spinal NRFit™ Needle 25 G x 3 1/2" (0.50 x 88.9 mm) + BD® Spinal Introducer NRFit™ Needle 20 G x 1.25" (0.90 × 31.8 mm)	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400229 - BD® Whitacre Spinal NRFit™ Needle 25 G x 4 1/16" (0.50 x 103.2 mm) + BD® Spinal Introducer NRFit™ Needle 20 G	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*

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x 1.25" (0.90 × 31.8 mm)						
400230 - BD® Whitacre Spinal NRFit™ Needle 27 G x 4 1/16" (0.40 x 103.2 mm) + BD® Spinal Introducer NRFit™ Needle 22 G x 1.25" (0.70 × 31.8 mm)	*95 06 0005 CP and 2020 04 0912 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400065 - BD® Quincke Spinal NRFit™ Needle 18 G x 3" (1.2 x 76.2 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400070 - BD® Quincke Spinal NRFit™ Needle 18 G x 3 1/2" (1.2 x 88.9 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400925 - BD® Quincke Spinal NRFit™ Needle 19 G x 3" (1.1 x 76.2 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400926 - BD® Quincke Spinal NRFit™ Needle 19 G x 3 1/2" (1.1 x 88.9 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400927 - BD® Quincke Spinal NRFit™ Needle 20 G x 1 1/2" (0.9 x 38.1 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400928 - BD® Quincke Spinal NRFit™ Needle 20 G x 3" (0.9 x 76.2 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400929 - BD® Quincke Spinal	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*

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NRFit™ Needle 20 G x 3 1/2" (0.9 x 88.9 mm)						
400072 - BD® Quincke Spinal NRFit™ Needle 22 G x 1 1/2" (0.7 x 38.1 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400073 - BD® Quincke Spinal NRFit™ Needle 22 G x 2 1/2" (0.7 x 63.5 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400077 - BD® Quincke Spinal NRFit™ Needle 22 G x 3" (0.7 x 76.2 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400079 - BD® Quincke Spinal NRFit™ Needle 22 G x 3 1/2" (0.7 x 88.9 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400930 - BD® Quincke Spinal NRFit™ Needle 23 G x 3 1/2" (0.6 x 88.9 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400063 - BD® Quincke Spinal NRFit™ Needle 25 G x 3" (0.5 x 76.2 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400089 - BD® Quincke Spinal NRFit™ Needle 25 G x 3 1/2" (0.5 x 88.9 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400931 - BD® Quincke Spinal NRFit™ Needle 26 G	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*

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x 3 1/2" (0.45 x 88.9 mm)						
400932 - BD® Quincke Spinal NRFit™ Needle 27 G x 3 1/2" (0.4 x 88.9 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400086 - BD® Quincke Spinal NRFit™ Needle 25 G x 2" (0.5 x 50.8 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400215 - BD® Quincke Spinal NRFit™ Needle 18 G x 6" (1.20 x 152.4 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400216 - BD® Quincke Spinal NRFit™ Needle 20 G x 6" (0.90 x 152.4 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400217 - BD® Quincke Spinal NRFit™ Needle 22 G x 5" (0.70 x 127 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400218 - BD® Quincke Spinal NRFit™ Needle 22 G x 7" (0.70 x 177.8 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400219 - BD® Quincke Spinal NRFit™ Needle 25 G x 4 11/16" (0.50 x 119.1 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400224 - BD® Quincke Spinal NRFit™ Needle 25 G x 3 1/2" (0.50 x 88.9 mm) + BD® Spinal	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*

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Introducer NRFit™ Needle 20 G x 1.25" (0.90 × 31.8 mm)						
400225 - BD® Quincke Spinal NRFit™ Needle 26 G x 3 1/2" (0.45 x 88.9 mm) + BD® Spinal Introducer NRFit™ Needle 20 G x 1.25" (0.90 × 31.8 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400226 - BD® Quincke Spinal NRFit™ Needle 27 G x 3 1/2" (0.40 x 88.9 mm) + BD® Spinal Introducer NRFit™ Needle 22 G x 1.25" (0.70 × 31.8 mm)	*95 06 0005 CP and 2020 04 0913 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
401995 - BD® Whitacre Pencil Point Spinal Needle 22 G × 3.50" (0.7 mm × 90 mm)	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405104 - BD® Whitacre Pencil Point Spinal Needle 24 G × 3.50" (0.55 mm × 90 mm)	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
402050 - BD® Whitacre Pencil Point Spinal Needle 25 G × 3.50" (0.50 mm × 90 mm)	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
402051 - BD® Whitacre Pencil Point Spinal Needle 27 G × 3.50" (0.40 mm × 90 mm)	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*

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405076 - BD® Whitacre Pencil Point Spinal Needle with Introducer 25 G × 3.50" (0.50 mm × 90 mm) + 20 G x 1.25" (0.9 mm × 32 mm)	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405075 - BD® Whitacre Pencil Point Spinal Needle with Introducer 27 G × 3.50" (0.40 mm × 90 mm) + 22 G x 1.25" (0.7 mm × 32 mm)	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405129 - BD® Whitacre Pencil Point Spinal Needle with Introducer 25 G × 3.50" (0.50 mm × 90 mm) + 20 G x 1.25" (0.9 mm × 32 mm) (India)	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405128 - BD® Whitacre Pencil Point Spinal Needle with Introducer 27 G × 3.50" (0.40 mm × 90 mm) + 22 G x 1.25" (0.7 mm × 32 mm (India)	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405112 - BD® Whitacre Pencil Point Spinal Needle with Introducer 25 G × 4.06" (0.50 mm × 103mm) + 20 G x 1.25" (0.9 mm × 32 mm)	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405113 - BD® Whitacre Pencil Point	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*

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Spinal Needle with Introducer 27 G × 4.06" (0.40 mm × 103 mm + 22 G x 1.25" (0.9 mm × 32 mm)						
405248 - BD® Quincke Type Point Spinal Needle 18 G x 3.50" (1.2 mm x 90 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405247 - BD® Quincke Type Spinal Needle Point 18 G x 3.00" (1.2 mm x 75 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405249 - BD® Quincke Type Point Spinal Needle 19 G x 3.00" (1.1 mm x 75 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405250 - BD® Quincke Type Point Spinal Needle 19 G x 3.50" (1.1 mm x 90 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405251 - BD® Quincke Type Point Spinal Needle 20 G × 1.50" (0.90 mm × 38 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405252 - BD® Quincke Type Point Spinal Needle 20 G × 3.00" (0.90 mm × 75 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405253 - BD® Quincke Type Point Spinal Needle 20 G ×	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*

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3.50" (0.90 mm × 90 mm)						
405254 - BD® Quincke Type Point Spinal Needle 22 G × 1.50" (0.7 mm × 38 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405255 - BD® Quincke Type Point Spinal Needle 22 G × 3.00" (0.7 mm × 75 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405244 - BD® Quincke Type Point Spinal Needle 22G × 2.50" (0.7 mm × 63 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405256 - BD® Quincke Type Point Spinal Needle 22 G × 3.50" (0.7 mm × 90 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405240 - BD® Quincke Type Point Spinal Needle 23 G × 3.50" (0.64 mm × 90 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405246 - BD® Quincke Type Point Spinal Needle 25 G × 3.00" (0.50 mm × 75 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405257 - BD® Quincke Type Point Spinal Needle 25 G × 3.50" (0.50 mm × 90 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405258 - BD® Quincke Type Point Spinal Needle 26 G ×	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*

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3.50" (0.45 mm × 90 mm)						
405259 - BD® Quincke Type Point Spinal Needle 27 G × 3.50" (0.40 mm × 90 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405125 - BD® Quincke Type Point Spinal Needle 18 G x 3.50" (1.2 mm x 90 mm) (India)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405123 - BD® Quincke Type Point Spinal Needle 20 G × 3.50" (0.90 mm × 90 mm) (India)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405121 - BD® Quincke Type Point Spinal Needle 22 G × 3.50" (0.70 mm × 90 mm) (India)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405120 - BD® Quincke Type Point Spinal Needle 23 G × 3.50" (0.64 mm × 90 mm) (India)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405122 - BD® Quincke Type Point Spinal Needle 25 G × 3.50" (0.50 mm × 90 mm) (India)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405124 - BD® Quincke Type Point Spinal Needle 26 G × 3.50" (0.45 mm × 90 mm) (India)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405127 - BD® Quincke Type Point Spinal Needle 27 G ×	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*

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3.50" (0.40 mm × 90 mm) (India)						
405084 - BD® Quincke Type Point Spinal Needle with Introducer 25 G × 3.50" (0.50 mm × 90 mm) + 20 G × 1.25″ (0.9 mm × 32 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405065 - BD® Quincke Type Point Spinal Needle with Introducer 26 G × 3.50" (0.45 mm × 90 mm) + 20 G × 1.25″ (0.9 mm × 32 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405069 - BD® Quincke Type Point Spinal Needle with Introducer 27 G × 3.50" (0.40 mm × 90 mm) + 22 G x 1.25″ (0.7 mm × 32 mm)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
405126 - BD® Quincke Type Point Spinal Needle with Introducer 27 G × 3.50" (0.40 mm × 90 mm) + 22 G x 1.25″ (0.7 mm × 32 mm) (India)	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
400076- BD® Spinal Introducer NRFit™ Needle 20 G x 1 1/4" (0.9 mm x 31.8 mm) Non-Sterile Bulk	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
400916 - BD® Spinal Introducer NRFit™ Needle 22 G x 1 1/4"	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*

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(0.7 mm x 31.8 mm) Non-Sterile Bulk						
400177- BD® Spinal Introducer NRFit™ Needle 20 G x 1 1/4" (0.9 mm x 31.8 mm)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
400919 - BD® Spinal Introducer NRFit™ Needle 22 G x 1 1/4" (0.7 mm x 31.8 mm)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
309744 - BD Plastipak™ 50 mL Luer-Lok™ Syringe with Blunt Fill Needle 18 G x 1" TW (1.2 x 25 mm)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
309745 - BD Plastipak™ 50 mL Luer-Lok™ Syringe with Blunt Fill Needle 18 G x 1 1/2" TW (1.2 x 40 mm)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
309746 - BD Plastipak™ 50 mL Luer-Lok™ Syringe (Amber) with Blunt Fill Needle 18 G x 1" TW (1.2 x 25 mm)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
309747 - BD Plastipak™ 50 mL Luer-Lok™ Syringe (Amber) with Blunt Fill Needle 18 G x 1 1/2" TW (1.2 x 40 mm)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
301229 - BD Plastipak™ 30 mL Luer-Lok™ Syringe	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*

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301189 - BD Plastipak™ 20 mL Luer-Lok™ Syringe	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300869 - BD Plastipak™ 50 mL Luer-Lok™ Syringe (Amber)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300865 - BD Plastipak™ 50 mL Luer-Lok™ Syringe	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
305959 - BD Plastipak™ 10 mL Luer-Lok™ Syringe	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300629 - BD Plastipak™ 20 mL Luer-Lok™ Syringe	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
303288 - BD Plastipak™ 50 mL Luer-Lok™ Syringe (India)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
301998 - BD Plastipak™ 20 mL Luer-Lok™ Syringe	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300223 - BD Plastipak™ 50 mL BD Luer-Lok™ Syringes (BNS)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
302055 - BD Plastipak™ 20 mL BD Luer-Lok™ Syringes (BNS)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
302237 - BD Plastipak™ 20 mL Luer-Lok™ Convenience Pack	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
302238 - BD Plastipak™ 50 mL Luer-Lok™ Convenience Pack	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*

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300605 - BD Plastipak™ 100 mL Catheter tip with Luer slip adaptor	*2000 06 0273 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300867 - BD Plastipak™ 50 mL Catheter Tip Syringe	*2000 06 0273 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300228 - BD Plastipak™ 50 mL Catheter Tip Syringes (BNS)	*2019 09 0898 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
301190 - BD Plastipak™ 20 mL Syringe with needle 21 G × 1 1/2" (0.8 × 40 mm)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
303175 - BD Plastipak™ 1 mL Syringe with needle 25 G × 5/8" (0.5 × 16 mm)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
303299 - BD Plastipak™ 1 mL Syringe with needle 27 G × 3/8" (0.4 × 10 mm)	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
301183 - BD Plastipak™ 20 mL Syringe	*2000 06 0273 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
303172 - BD Plastipak™ 1 mL Syringe	*2000 06 0273 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300866 - BD Plastipak™ 50 mL Syringe	*2000 06 0273 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300613 - BD Plastipak™ 20 mL Syringe	*2000 06 0273 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*

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301231 - BD Plastipak™ 30 mL Syringe	*2000 06 0273 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300224 - BD Plastipak™ 50 mL Syringes (BNS)	*2019 09 0898 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300220 - BD Plastipak™ 20 mL Syringes (BNS)	*2019 09 0898 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
300328 - BD Plastipak™ 1 mL Syringes (BNS)	*2019 09 0898 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*

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12 March 2024

Notified Body Confirmation Letter
Reference: EU2023-607/ 764888

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:

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SRN Number: ES-MF-000016479

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.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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 Plastipak™ Luer-Lok™ Syringe (without needle) **Basic UDI-DI: 038290SYLPEAGDM5** Listed on MDD certificate as: *Three-piece syringes without needle;* *Sterile BD Plastipak™ Luer-Lok™ syringes;* *Amber color syringes of: 50 ml*	Class IIa	N/A	Certificate reference: 95 06 0005 CP; expiry date 2024-05-24, Number: 0318
BD Plastipak™ Luer-Lok™ Convenience Pack **(without needle)** **Basic UDI-DI: 038290UOKRIXNENG** Listed on MDD certificate as: *Three-piece syringes without needle;* *Sterile BD Plastipak™ Luer-Lok™ syringes;*	Class IIa	'N/A'	Certificate reference: 95 06 0005 CP; expiry date 2024-05-24, NB number 0318

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
Sizes: *Convenience Pack of syringes of: 20 ml,* *Convenience Pack of syringes of: 50 ml*			
BD Plastipak™ Catheter Tip Syringe **Basic UDI-DI: 038290TWOWNMYHW3** Listed on the MDD certificate as: *Syringes without needle, Insulin syringes; Three-piece sterile BD Plastipak™ syringes without needle; Syringes with Catheter Tip connection* *Sizes:* *Syringes of: 50 ml* *Syringes of: 100 ml*	Class I device placed on the market in sterile condition Class I device with a measuring function	'N/A'	Certificate reference**: 2000 06 0273 CP; expiry date 2024-05-24, NB number 0318**
BD Plastipak™ Catheter Tip Syringe (Bulk Non Sterile) **Basic UDI-DI: 038290IHOCSHLU8L** Listed on the MDD certificate as: *Syringes without needle; Non-sterile three-piece syringes without needle BD Plastipak™; Syringes with Catheter Tip connection* *Size:* *Syringes of: 50 ml*	Class I device with a measuring function	'N/A'	Certificate reference: **MDD/AIMDD Certificate #2019 09 0898 CP; expiry date 2024-05-24, NB# 0318**
BD Plastipak™ Luer-Slip Syringe (without needle)	Class I device placed on the	'N/A'	Certificate reference:

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
Basic UDI-DI: 038290SRGVPAAEKC Listed on the MDD certificate as: *Syringes without needle, Insulin syringes; Three-piece sterile BD Plastipak™ syringes without needle; Luer-Slip syringes* *Sizes:* *Syringes of: 1 ml* *Syringes of: 2 ml* *Syringes of: 5 ml* *Syringes of: 10 ml* *Syringes of: 20 ml* *Syringes of: 30 ml* *Syringes of: 50 ml*	market in sterile condition Class I device with a measuring function		**#2000 06 0273 CP; expiry date 2024-05-24, NB number 0318**
BD Plastipak™ Luer-Slip Syringe (without needle Bulk Non Sterile) **Basic UDI-DI:** **038290XOKHQOIDLM** Listed on the MDD certificate as: *Syringes without needle; Non-sterile three-piece syringes without needle BD Plastipak™; Luer-Slip syringes* *Sizes:* *Syringes of: 1 ml* *Syringes of: 20 ml* *Syringes of: 50 ml*	Class I device with a measuring function	'N/A'	Certificate reference: **#2019 09 0898 CP; expiry date 2024-05-24, NB# 031**8
BD Whitacre Spinal Needle	Class III	'N/A'	Certificate reference:

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
Basic UDI-DI: 038290JPCVIFOCBR Listed on the MDD certificate as: *Spinal needles; Whitacre Pencil Point Spinal Needles; Sterile Whitacre Pencil Point Spinal Needle: BD Whitacre Needle* *Sizes:* *22G × 3.50" (0.7 × 90 mm)* *24G × 3.50" (0.55 × 90 mm)* *25G × 3.50" (0.50 × 90 mm)* *27G × 3.50" (0.40 × 90 mm)*			#95 06 0005 CP and 2010 02 0700 ET; expiry date 2024-05-24, NB# 0318
BD Whitacre Spinal Needle Set (Spinal needle + introducer) **Basic UDI-DI: 038290KITVJVYYLK** Listed on the MDD certificates as: *Sterile Whitacre Pencil Point Spinal Needle with introducer set, BD Whitacre Needle* *Sizes:* *25G × 3.50" (0.50 × 90 mm) with introducer 20G × 1.25" (0.9 × 32 mm)* *25G × 4.06" (0.50 × 103 mm) with introducer 20G × 1.25" (0.9 × 32 mm)* *27G × 3.50" (0.40 × 90 mm) with introducer 22G × 1.25" (0.7 × 32 mm)* *27G × 4.06"(0.40 × 103 mm) with introducer 22G × 1.25" (0.7 × 32 mm)*	Class III	'N/A'	Certificate reference: #95 06 0005 CP and 2010 02 0700 ET; expiry date 2024-05-24, NB# 0318, to be read in conjunction with amending AEMPS letter dated 16 November 2021, ON0318/GH/JC/PS/95 04 0005
BD Quincke Spinal Needle	Class III	'N/A'	Certificate reference:

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
Basic UDI-DI: 038290HFPYXWDAGC Listed on the MDD certificate as: *Spinal needles; Spinal needle Quincke type point; Sterile spinal needle Quincke type point: BD Spinal Needle* *Sizes:* *18G × 3.00" (1.2 × 75 mm)* *18G × 3.50" (1.2 × 90 mm)* *19G × 3.00" (1.1 × 75 mm)* *19G × 3.50" (1.1 × 90 mm)* *20G × 1.50" (0.90 × 38 mm)* *20G × 3.00" (0.90 × 75 mm)* *20G × 3.50" (0.90 × 90 mm)* *22G × 1.50" (0.7 × 38 mm)* *22G × 2.50" (0.7 × 63 mm)* *22G × 3.00" (0.7 × 75 mm)* *22G × 3.50" (0.7 × 90 mm)* *23G × 3.50" (0.64 × 90 mm)* *25G × 3.00" (0.50 × 75 mm)* *25G × 3.50" (0.50 × 90 mm)* *26G × 3.50" (0.45 × 90 mm)* *27G × 3.50" (0.40 × 90 mm)*			#95 06 0005 CP and 2010 02 0701 ET; expiry date 2024-05-24, NB# 0318
BD Quincke Spinal Needle Set (Spinal needle + introducer) **Basic UDI-DI:** **038290JBDWOAQF5Y** Listed on the MDD certificate as:	Class III	'N/A'	Certificate reference: MDD/AIMDD Certificate #95 06 0005 CP and 2010 02 0701 ET; expiry date 2024-05-24, NB# 0318, to be read in conjunction with amending AEMPS letter dated 15

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
Spinal needles; Spinal needle Quincke type point; Sterile spinal needle Quincke type point with introducer set: BD Spinal Needle *Sizes:* *25G × 3.50" (0.50 × 90 mm) con introductor / with introducer 20G × 1.25" (0.9 × 32 mm)* *26G × 3.50" (0.45 × 90 mm) con introductor / with introducer 20G × 1.25" (0.9 × 32 mm)* *27G × 3.50" (0.40 × 90 mm) con introductor / with introducer 22G × 1.25" (0.7 × 32 mm)*			November 2021 S/REF CNCps ID: 90811
BD Quincke Spinal NRFitTM Needle **Basic UDI-DI: 038290WAHENDUTA4** Listed on the MDD certificate as: *Spinal needles; BD Quincke Spinal NRFit™ Needles;Sterile BD Quincke Spinal NRFit™ Needles BD Quincke Spinal NRFit™ Needle* *Sizes:* *25G × 3.00″ (0.5 × 76.2 mm)* *18G × 3.00″ (1.2 × 76.2 mm)* *18G × 3.50″ (1.2 × 88.9 mm)* *22G × 1.50″ (0.7 × 38.1 mm)* *22G × 2.50″ (0.7 × 63.5 mm)* *22G × 3.00″ (0.7 × 76.2 mm)* *22G × 3.50″ (0.7 × 88.9 mm)* *25G × 3.50″ (0.5 × 88.9 mm)* *25G × 2.00″ (0.5 × 50.8 mm)* *19G × 3.00″ (1.1 × 76.2 mm)*	Class III	N/A	Certificate reference: #95 06 0005 CP and 2020 04 0913 ET; expiry date 2024-05-24, NB# 0318

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
19G × 3.50″ (1.1 × 88.9 mm) *20G × 1.50″ (0.9 × 38.1 mm)* *20G × 3.00″ (0.9 × 76.2 mm)* *20G × 3.50″ (0.9 × 88.9 mm)* *23G × 3.50″ (0.6 × 88.9 mm)* *26G × 3.50″ (0.45 × 88.9 mm)* *27G × 3.50″ (0.4 × 88.9 mm)*			
BD Quincke Spinal NRFitTM Needle Set (NRFit Spinal Needle + introducer) **Basic UDI-DI: 038290MIVCNTRJEZ** Listed on the MDD certificate as: *Spinal needles; BD Quincke Spinal NRFit™ Needles;Sterile BD Quincke spinal NRFit™ Needle with introducer set. BD Quincke Spinal NRFit™ Needle Set* *Sizes:* *25G × 3.50″ (0.50 × 88.9 mm) con introductor / with introducer 20 G × 1.25″ (0.90 × 31.8 mm)* *27G × 3.50″ (0.40 × 88.9 mm) con introductor / with introducer 22 G × 1.25″ (0.70 × 31.8 mm)* *26G × 3.50″ (0.45 × 88.9 mm) with introducer / with introducer 20G x 1.25" (0.90 x 31.8 mm)*	Class III	N/A	Certificate reference: #95 06 0005 CP and 2020 04 0913 ET; expiry date 2024-05-24, NB# 0318, to be read in conjunction with amending AEMPS letter dated 15 november 2021, S/REF CNCps ID: 92262
BD Whitacre Spinal NRFit™ Needle **Basic UDI-DI: 038290RFMMCNXCCX**	Class III	N/A	Certificate reference: #95 06 005 CP and 2020 04 0912 ET; expiry date 2024-05-24, NB# 0318

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
Listed on the MDD certificate as: *Spinal needles; BD Whitacre Spinal NRFit™ Needles; Sterile BD Whitacre Spinal NRFit™ Needle BD Whitacre Spinal NRFit™ Needle* *Sizes:* *25G × 4.06″ (0.50 × 103.2 mm)* *25G × 4.70″ (0.50 × 119.1 mm)* *27G × 4.06″ (0.40 × 103.2 mm)* *27G × 4.70″ (0.40 × 119.1 mm)* *22G × 3.50″ (0.70 × 88.9 mm)* *24G × 3.50″ (0.55 × 88.9 mm)* *25G × 3.50″ (0.50 × 88.9 mm)* *27G × 3.50″ (0.40 × 88.9 mm)*			
BD Whitacre Spinal NRFit™ Needle Set (NRFit Spinal Needle + introducer) **Basic UDI-DI: 038290EDURMMPSBE** Listed on the MDD certificate as: *Spinal needles; BD Whitacre Spinal NRFit™ Needles; Sterile BD Whitacre Spinal NRFit™ Needle with introducer set. BD Whitacre Spinal NRFit™ Needle Set.* *Sizes:* *27G × 3.50″ (0.40 × 88.9 mm) with introducer 22G × 1.25″ (0.70 × 31.8 mm)* *25G × 3.50″ (0.50 × 88.9 mm) with introducer 20G × 1.25″ (0.90 × 31.8 mm)*	Class III	N/A	Certificate reference: #95 06 005 CP and 2020 04 0912 ET; expiry date 2024-05-24, NB# 0318

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
25G × 4.06″ (0.50 × 103.2 mm) with introducer 20G × 1.25″ (0.90 × 31.8 mm) *27G × 4.06″ (0.40 × 103.2 mm) with introducer 22G × 1.25″ (0.70 × 31.8 mm)*			
BD Spinal Introducer NRFit Needle **Basic UDI-DI (Sterile): 038290XGKVYVIXRA** Listed on the MDD certificate as: *Needle introducer; Sterile BD Spinal needle introducer NRFit™ BD Spinal needle introducer NRFit™* *Sizes:* *20G × 1.25″ (0.90 × 31.8 mm)* *22G × 1.25″ (0.70 × 31.8 mm)*	Class IIa	N/A	Certificate reference: #95 06 0005 CP; expiry date 2024-05-24, NB# 0318
BD Discardit II Syringe **(with Needle)** **Basic UDI-DI (Microlance needle): 038290HLQCKJFL8D** Listed on the MDD certificate as: *Syringes with needle; Sterile two-piece syringes with needle BD Discardit™ II* *Sizes:* *Syringes of: 2 ml:* *With needle: 21G × ⅝″ (0.8 × 16 mm)* *With needle: 22G × 1 ½″ (0.7 × 40 mm)* *With needle: 23G × 1″ (0.6 × 25 mm)*	Class IIa	N/A	Certificate reference: #95 06 0006 CP; expiry date 2024-05-26, NB# 0318 MDD Certificate issued to BECTON DICKINSON S.A. C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)

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
With needle: 24G × 1″ (0.55 × 25 mm) *Syringes of: 5 ml* *With needle:21G × 1 ½″ (0.8 × 40 mm)* *Syringes of: 10 ml* *With needle: 21G × 1 ½″ (0.8 × 40 mm)* *With needle: 21G × 1″ (0.8 × 25 mm)* *Syringes of: 20 ml* *With needle: 21G × 1 ½″ (0.8 × 40 mm)*			
BD Discardit II Non Sterile Bulk Syringe (without needle) **Basic UDI-DI: 038290IWCCNEZKAT** Listed on the MDD certificate as: *Syringes without needle; Non-sterile syringes without needle; Two-piece syringes BD Discardit™ II* *sizes:* *Syringes of: 2 ml* *Syringes of: 5 ml* *Syringes of: 10 ml* *Syringes of: 20 ml*	Class I device with a measuring function	N/A	Certificate reference: **MDD/AIMDD Certificate #99 03 0213 CP; expiry date 2024-05-26, NB# 0318** MDD Certificate issued to BECTON DICKINSON S.A. C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)
BD Discardit II Syringe **(without needle)** **Basic UDI-DI: 038290DDEODFOLXL**	Class I device placed on the market in sterile condition	N/A	Certificate reference: MDD/AIMDD Certificate #2000 06 0272 CP; expiry date 2024-05-26, NB# 0318

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
Listed on the MDD certificate as: *Syringes without needle and syringes with blunt fill needle; Sterile syringes without needle; Two-piece syringes BD Discardit™ II* *Syringes of: 2 ml* *Syringes of: 5 ml* *Syringes of: 10 ml* *Syringes of: 20 ml*	Class I device with a measuring function		MDD Certificate issued to BECTON DICKINSON S.A. C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)
BD MicrolanceTM 3 Needle **Basic UDI-DI: 038290MLFUVFGJET** *Listed on the MDD certificate as:* *Needles; Sterile hypodermic needles BD Microlance ™ 3* *Sizes:* *Needle 20G × 1 ½″ (0.9 × 40 mm)* *Needle 20G × 1″ (0.9 × 25 mm)* *Needle 21G × 1″ (0.8 × 25 mm)* *Needle 21G × 1 ½″ (0.8 × 40 mm)* *Needle 21G × ⅝″ (0.8 × 16 mm)* *Needle 22G × 1 ¼″ (0.7 × 30 mm)* *Needle 22G × 1 ½″ (0.7 × 40 mm)* *Needle 22G × 1″ (0.7 × 25 mm)* *Needle 23G × 1 ¼″ (0.6 × 30 mm)* *Needle 23G × 1″ (0.6 × 25 mm)* *Needle 22G × 2″ (0.7 × 50 mm)* *Needle 26G × ⅜″ (0.45 × 10 mm)* *Needle 25G × 1″ (0.5 × 25 mm)* *Needle 25G × ⅝″ (0.5 × 16 mm)*	Class IIa	N/A	Certificate reference: MDD/AIMDD Certificate #95 06 0006 CP; expiry date 2024-05-26, NB# 0318 MDD Certificate issued to BECTON DICKINSON S.A. C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)

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
Needle 27G × ½″ (0.4 × 13 mm) *Needle 16G × 1 ½″ (1.6 × 40 mm)* *Needle 21G × 2″ (0.8 × 50 mm)* *Needle 19G × 1 ½″ (1.1 × 40 mm)* *Needle 19G × 1″ (1.1 × 25 mm)* *Needle 19G × 2″ (1.1 × 50 mm)* *Needle 18G × 2″ (1.2 × 50 mm)* *Needle 27G × ¾″ (0.4 × 19 mm)* *Needle 26G × ½″ (0.45 × 13 mm)* *Needle 30G × ½″ (0.3 × 13 mm)* *Needle 24G × 1″ (0.55 × 25 mm)* *Needle 26G × ⅝″ (0.45 × 16 mm)* *Needle 18G × 1 ½″ (1.2 × 40 mm)* *Needle 27G × ⅜″ (0.4 × 10 mm)* *Needle 23G × 1 ½″ (0.6 × 40 mm)*			
BD Microlance TM 3 Non Sterile Bulk Needle **Basic UDI-DI: 038290MVVIHDPPLC** Listed on the MDD certificate as: *Needles; Non-sterile hypodermic needles BD Microlance™ 3* *Needle 25G × ⅝″ (0.5 × 16 mm)* *Needle 21G × ⅝″ (0.8 × 16 mm)* *Needle 25G × 1″ (0.5 × 25 mm)* *Needle 21G × 1″ (0.8 × 25 mm)* *Needle 21G × 1 ½″ (0.8 × 40 mm)* *Needle 20G × 1 ½″ (0.9 × 40 mm)*	Class IIa	N/A	Certificate reference: #95 06 0006 CP; expiry date 2024-05-26, NB# 0318, to be read in conjunction with amending AEMPS letter dated 10 March 2022 regarding and change submitted 22 December 2021, S/REF 94331 MDD Certificate issued to BECTON DICKINSON S.A. C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)

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
Needle 22G × 1 ¼″ (0.7 × 30 mm) *Needle 30G × ½″ (0.3 × 13 mm)* *Needle 27G × ½″ (0.4 × 13 mm)* *Needle 19G × 1 ½″ (1.1 × 40 mm)* *Needle 14G × 1 ¼″ (2.1 × 30 mm)* *Needle 26G × ½″ (0.45 × 13 mm)* *Needle 26G × ⅜″ (0.45 × 10 mm)* *Needle 23G × 1″ (0.6 × 25 mm)* *Needle 21G × 2″ (0.8 × 50 mm)* *Needle 18G × 2″ (1.2 × 50 mm)* *Needle 27G × ¾″ (0.4 × 19 mm)* *Needle 24G × 1″ (0.55 × 25 mm)* *Needle 18G × 1 ½″ (1.2 × 40 mm)* *Needle 22G × 1″ (0.7 × 25 mm)* *Needle 22G × 1 ½″ (0.7 × 40 mm)* *Needle 23G × 1 ¼″ (0.6 × 30 mm)* *New non-sterile variant of the MicrolanceTM 3 27G x 3/8″ (0.4 x 10 mm) needle*			
BD SoloShotTM Mini Syringe **Basic UDI-DI: 038290CDXRXOBXD6** Listed on the MDD certificate as: *Syringes with needle; Sterile auto-disable two-piece syringes with integrated cannula BD SoloShot™ Mini* *Sizes:* *2.6.a Syringes of: 0.5 ml*	Class IIa	N/A	Certificate reference: #95 06 0006 CP; expiry date 2024-05-26, NB# 0318 MDD Certificate issued to BECTON DICKINSON S.A. C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)

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
2.6.a.1 With needle: 23G × 1″ (0.6 × 25 mm) *2.6.a.2 With needle: 24G × ¾″ (0.55 × 19 mm)* *2.6.a.3 With needle: 25G × ⅝″ (0.5 × 16 mm)* *2.6.a.4 With needle: 25G × 1″ (0.5 × 25 mm)* *2.6.b Syringes of: 0.1 ml* *2.6.b.1 With needle: 27G × ⅜″ (0.4 × 10 mm)* *2.6.c Syringes of: 0.05 ml* *2.6.c.1 With needle: 27G × ⅜″ (0.4 × 10 mm)* *2.5.d. Syringes of 0.2 ml* *2.5.d.1. With needle: 23G × 1″ (0.6 × 25 mm)* *2.5.e. Syringes of 0.3 ml* *2.5.e.1. With needle: 23G × 1″ (0.6 × 25 mm)* *2.5.f. Syringes of 0.4 ml* *2.5.f.1. With needle: 23G × 1″ (0.6 × 25 mm)*			
BD SoloShotTM IX Syringe **Basic UDI-DI: 038290MJTMIQJVGL**	Class IIa	N/A	Certificate reference: #95 06 0006 CP; expiry date 2024-05-26, NB# 0318 MDD Certificate issued to BECTON DICKINSON S.A.

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
Listed on the MDD certificate as: *Syringes with needle; Sterile auto-disable two piece syringes with integrated cannula BD SoloShot TM IX* *Sizes:* *Syringes of: 0.5 ml* *With needle: 23G × 1″ (0.6 × 25 mm)* *With needle: 24G × ¾″ (0.55 × 19 mm)* *With needle: 24G × 1″ (0.55 × 25 mm)* *With needle: 25G × ⅝″ (0.5 × 16 mm)* *With needle: 25G × 1″ (0.5 × 25 mm)* *Syringes of: 1 ml* *With needles: 22G × 1″ (0.7 × 25 mm)* *With needle: 23G × 1″ (0.6 × 25 mm)*			C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)
BD Flu+ Syringe **Basic UDI-DI: 038290VFCSOUDWGE** Listed on the MDD certificate as: *Syringes with needle; Sterile two-piece syringes with integrated cannula BD Flu+* *Sizes:* *With needle: 23G × 1″ (0.6 × 25 mm)* *With needle: 25G × ⅝″ (0.5 × 16 mm)* *With needle: 25G × 1″ (0.5 × 25 mm)* *With needle: 23G × 1″ (0.6 × 25 mm) 0.1 – 1 ml*	Class IIa	N/A	Certificate reference: #95 06 0006 CP; expiry date 2024-05-26, NB# 0318, to be read in conjunction with amending AEMPS letter dated 20 October 2021 regarding and change submitted 20 August 2021, S / REF: 90802 MDD Certificate issued to BECTON DICKINSON S.A., C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)

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
With needle: 25G × 1″ (0.5 x 25 mm) 0.1 – 1 ml			
BD Emerald TM Syringe **(without needle)** **Basic UDI-DI: 038290PDVJVUZUKV** Listed on the MDD certificate as: *Syringes without needle and syringes with blunt fill needle; Sterile syringes without needle; Sterile three-piece syringes BD Emerald™* *Sizes:* *Syringes of: 2 ml* *Syringes of: 5 ml*	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	Certificate reference: #2000 06 0272 CP; expiry date 2024-05-26, NB# 0318 MDD Certificate issued to BECTON DICKINSON S.A., C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)
BD EmeraldTM Syringe **(with needle)** **Basic UDI-DI (Microlance needle): 038290JGXPPFFCE5** Listed on the MDD certificate as: *Sterile three-piece syringes with needle BD Emerald™;* *Syringes of 2 ml and needle side by side:* *With needle: 21G × 1 ½″ (0.8 × 40 mm)* *With needle: 23G × 1″ (0.6 × 25 mm)* *Syringes of 2 ml and pre-attached needle* *With needle: 21G × 1 ½″ (0.8 × 40 mm)*	Class IIa	N/A	Certificate reference: #95 06 0006 CP; expiry date 2024-05-26, NB# 0318 MDD Certificate issued to BECTON DICKINSON S.A., C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)

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
With needle: 23G × 1″ (0.6 × 25 mm) *With needle: 25G × ⅝″ (0.5 × 16 mm)* *Syringes of 5 ml and needle side by side* *With needle: 21G × 1 ½″ (0.8 × 40 mm)* *With needle: 23G × 1″ (0.6 × 25 mm)* *With needle: 24G × 1″ (0.55 × 25 mm)* *Syringes of 5 ml and pre-attached needle* *With needle: 21G × 1 ½″ (0.8 × 40 mm)* *With needle: 23G × 1″ (0.6 × 25 mm)* *Syringes of 10 ml and needle side by side* *With needle: 21G × 1 ½″ (0.8 × 40 mm)* *With needle: 21G × 1″ (0.8 × 25 mm)* *Syringes of 10 ml and pre-attached needle* *With needle: 21G × 1 ½″ (0.8 × 40 mm)*			
BD EmeraldTM Non Sterile Bulk Syringe (without needle) **Basic UDI-DI: 038290ZDNJQVHDJV**	Class I device with a measuring function	N/A	Certificate reference: #99 03 0213 CP; expiry date 2024-05-26, NB# 0318

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
Listed on the MDD certificate as: *Syringes without needle; Non-sterile syringes without needle; Three-piece bulk syringes BD Emerald™* *Sizes:* *Syringes of: 2 ml* *Syringes of: 5 ml* *Syringes of: 10 ml*			MDD Certificate issued to BECTON DICKINSON S.A., C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)
BD EmeraldTM PRO Syringe **(with needle)** **Basic UDI-DI (Microlance needle): 038290GRPEWKKVF5** Listed on the MDD certificate as: *Sterile three-piece syringes with reuse prevention and needle BD Emerald™ PRO;* *Syringes of 2 ml and needle side by side* *With needle: 21G × 1 ½″ (0.8 × 40 mm)* *With needle: 23G × 1″ (0.6 × 25 mm)* *Syringes of 5 ml and needle side by side* *With needle: 21G × 1 ½″ (0.8 × 40 mm)* *With needle: 23G × 1″ (0.6 × 25 mm)* *Syringes of 10 ml and needle side by side*	Class IIa	N/A	Certificate reference: #95 06 0006 CP; expiry date 2024-05-26, NB# 0318 MDD Certificate issued to BECTON DICKINSON S.A., C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)

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
With needle: 21G × 1 ½″ (0.8 × 40 mm)			
BD Blunt Fill Needle **Basic UDI-DI: 38290NGGTJRVACW** Listed on the MDD certificate as: *Blunt fill needle; Sterile needle to aspirate pharmaceutical fluids from vials or ampoules; Needle BD Blunt Fill Needle* *Size: 18G × 1 ½″ (1.2 × 40 mm)*	Class I device placed on the market in sterile condition	N/A	Certificate reference: #2015 03 0838 CP; expiry date 2024-05-26, NB# 0318 MDD Certificate issued to BECTON DICKINSON S.A., C/ Mequinenza, s/n. E-22520 FRAGA (Huesca) España (Part of the same larger organisation)
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/03/12	Initial issue

Becton Dickinson S.A.
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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. Crta. Mequinenza s/n 22520 – Fraga HUESCA – ESPAÑA
Products: *Productos:*	BD Plastipak™ syringes with needle *Jeringas BD Plastipak™ con aguja* See list of references attached / *ver listado de referencias adjunto.*
Classification: *Clasificación:*	Class IIa, as per Rule 6 of Annex IX of the Medical Devices Directive 93/42/EEC (June 14th, 1993) *Clase IIa, según la Regla 6 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 / 38501 GMDN Term / Término: 47017 General-purpose syringe / *Jeringa de uso general* GMDN Term / Término: 38501 Insulin syringe / *Jeringa para insulina*

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. 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. Toda la documentación de soporte se guarda en las instalaciones del fabricante.

List of Harmonized Standards: *Lista de Normas Armonizadas:*	UNE-EN 556-1 :2001 + AC :2006, EN 1707:1996, EN ISO 10993 Series, EN ISO 11737-2:2009, EN ISO 13485:2016/AC:2018, EN ISO 15223-1:2016
Non-Harmonized standards: *Normas No Armonizadas:*	EN ISO 7864:2016, EN ISO 7886-1:2018, EN ISO 8537:2016, EN ISO 9626:2016, EN ISO 6009:2016, EN ISO 10993-10:2013, UNE-EN ISO 11135:2015, EN 1041:2008+A1:2013, EN ISO 11138-2:2017, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, EN ISO 14971:2019
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:*	95 06 0005 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* *Reference/referencia: 303299: May 13th, 2021, 13 de mayo de 2021*

Date / *Fecha:* October 11, 2021 / *11 de octubre de 2021*

Lourdes López
General Director / Directora General
Becton Dickinson S.A.

Signature / Firma: DocuSigned by: LOURDES LOPEZ 45D7EA7E2E3A4C8...

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PRODUCT LIST
LISTA DE PRODUCTOS

STERILE BD PLASTIPAK™ LUER-SLIP SYRINGES WITH BD MICROLANCE™ 3 NEEDLE
JERINGAS ESTÉRILES BD PLASTIPAK™ CONO LUER CON AGUJA BD MICROLANCE™ 3

Reference *Referencia*	**Description** *Descripción*		
300829	BD Plastipak™ syringe with needle (10 Pack France) *Jeringa BD Plastipak™ con aguja (10 Pack France)*	1 mL	26G × ⅜" (0.45 × 10 mm)
301190	BD Plastipak™ syringe with needle *Jeringa BD Plastipak™ con aguja*	20 mL	21G × 1½" (0.8 × 40 mm)
303175	BD Plastipak™ syringe with needle *Jeringa BD Plastipak™ con aguja*	1 mL	25G × ⅝" (0.5 × 16 mm)
303176	BD Plastipak™ syringe with needle *Jeringa BD Plastipak™ con aguja*	1 mL	26G × ⅜" (0.45 × 10 mm)
309742	BD Plastipak™ syringe with needle *Jeringa BD Plastipak™ con aguja*	50 mL	14G × 1¼" (2.1 × 30 mm)
309743	BD Plastipak™ syringe with needle *Jeringa BD Plastipak™ con aguja*	50 mL	14G × 1¼" (2.1 × 30 mm)
303299	BD Plastipak™ syringe with needle *Jeringa BD Plastipak™ con aguja*	1 mL	27G × ⅜" (0.4 × 10 mm)

BD PLASTIPAK THREE-PIECE INSULIN LUER-SLIP SYRINGES WITH NEEDLE
JERINGAS DE TRES PIEZAS BD PLASTIPAK CONO LUER CON AGUJA PARA INSULINA

Reference *Referencia*	**Description** *Descripción*		
303177	BD Plastipak™ Insulin syringe U-40 with needle *Jeringa BD Plastipak™ de insulina U-40 con aguja*	1 mL	30G × ½" (0.3 × 13 mm)
303178	BD Plastipak™ Insulin syringe U-100 with needle *Jeringa BD Plastipak™ de insulina U-100 con aguja*	1 mL	26G × ⅜" (0.45 × 10 mm)
303179	BD Plastipak™ Insulin syringe U-100 with needle *Jeringa BD Plastipak™ de insulina U-100 con aguja*	1 mL	25G × ⅝" (0.5 × 16 mm)

STERILE BD PERFUSION SYRINGES WITH BD MICROLANCE™ 3 NEEDLE
JERINGAS ESTÉRILES BD PERFUSION CON AGUJA BD MICROLANCE™ 3

Reference *Referencia*	**Description** *Descripción*		
300136	BD Perfusion syringe with needle *Jeringa BD Perfusión con aguja*	50 mL	14G × 1¼" (2.1 × 30 mm)
300138	BD Perfusion syringe with needle *Jeringa BD Perfusión con aguja*	50 mL	14G × 1¼" (2.1 × 30 mm)

Date / *Fecha:* June 1, 2021 / *1 de junio de 2021*

Lourdes López
General Director / Directora General

Signature / Firma: DocuSigned by: LOURDES LOPEZ 45D7EA7E2E3A4C8...