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

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 / 20-Nov-2023**

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)
Agujas espinales BD Whitacre NRFit™ estériles / Sterile BD Whitacre Spinal NRFit™ Needles. BD Whitacre Spinal NRFit™ Needles	*95 06 0005 CP and 2020_04_0912_ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
Set Aguja espinal BD Whitacre NRFit™ con introductor, estéril / Sterile BD Whitacre Spinal NRFit™ Needle with introducer set. BD Whitacre Spinal NRFit™ Needle Set.	*95 06 0005 CP and 2020_04_0912_ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
Agujas espinales BD Quincke NRFit™ estériles / Sterile BD Quincke Spinal NRFit™ Needles. BD Quincke Spinal NRFit™ Needles	*95 06 0005 CP and 2020_04_0913_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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Set Aguja espinal BD Quincke NRFit™ con introductor, estéril / Sterile BD Quincke spinal NRFit™ Needle with introducer set. BD Quincke Spinal NRFit™ Needle Set	*95 06 0005 CP and 2020_04_0913_ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
Aguja espinal Whitacre punta tipo lápiz estéril / Sterile Whitacre Pencil Point Spinal Needle: BD Whitacre Needle	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
Set aguja espinal Whitacre punta tipo lápiz con introductor, estéril / Sterile Whitacre Pencil Point Spinal Needle with introducer set: BD Whitacre Needle	*95 06 0005 CP and 2010 02 0700 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
Aguja espinal estéril punta tipo Quincke / Sterile spinal needle Quincke type point: BD Spinal Needle	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
Set aguja espinal punta tipo Quincke con introductor, estéril / Sterile spinal needle Quincke type point with introducer set: BD Spinal Needle	*95 06 0005 CP and 2010 02 0701 ET*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2027-12-31*	*N/A*
BD Aguja introductora espinal NRFit™ estéril / Sterile BD Spinal needle introducer	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*

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NRFit™ BD Spinal needle introducer NRFit™						
BD Aguja introductora espinal NRFit™ no estéril / Non-sterile BD Spinal needle introducer NRFit™ BD Spinal needle introducer NRFit™	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
Jeringas estériles BD Plastipak™ Luer-Lok™ con aguja Blunt / Sterile BD Plastipak™ Luer-Lok™ syringes with Blunt Fill Needle	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
Jeringas estériles BD Plastipak™ Luer-Lok™ con aguja BD Microlance™ 3 / Sterile BD Plastipak™ Luer-Lok™ syringes with BD Microlance™ 3 needles	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
Jeringas estériles BD Plastipak™ Luer-Lok™ / Sterile BD Plastipak™ Luer-Lok™ syringes	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
Jeringas no estériles BD Plastipak™ Luer-Lok™ / Non-sterile BD Plastipak™ Luer-Lok™ syringes	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
Jeringas estériles BD Plastipak™ Luer-Lok™ / Sterile BD	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*

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Plastipak™ Luer-Lok™ syringes Envase Convenience de jeringas de: / Convenience Pack of syringes of: 20 ml						
Jeringas estériles de tres piezas sin aguja BD Plastipak™ / Three-piece sterile BD Plastipak™ syringes without needle Jeringas con conexión Cono Catéter / Syringes with Catheter Tip connection	*2000 06 0273 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
Jeringas no estériles de tres piezas sin aguja BD Plastipak™ / Non-sterile three-piece syringes without needle BD Plastipak™ Jeringas con conexión Cono Catéter / Syringes with Catheter Tip connection	*2019 09 0898 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
Jeringas estériles BD Plastipak™ cono Luer con aguja BD Microlance™ 3 / Sterile BD Plastipak™ Luer-Slip syringes with BD Microlance™ 3 needle	*95 06 0005 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*
Jeringas estériles de tres piezas sin aguja	*2000 06 0273 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*

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BD Plastipak™ / Three-piece sterile BD Plastipak™ syringes without needle Jeringas cono Luer / Luer-Slip syringes						
Jeringas no estériles de tres piezas sin aguja BD Plastipak™ / Non-sterile three-piece syringes without needle BD Plastipak™ Jeringas cono Luer / Luer-Slip syringes	*2019 09 0898 CP*	*2024-05-24*	*AEMPS 0318*	*BSI 2797*	*2028-12-31*	*N/A*