MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

CERTIFICADO CE DE GARANTÍA DE CALIDAD DE LA PRODUCCIÓN
de acuerdo con el Anexo V de la Directiva 93/42/CEE
EC PRODUCTION QUALITY ASSURANCE CERTIFICATE
in accordance with Annex V of Directive 93/42/EEC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
95 06 0005 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/*For the product*:

Categoría/*Category*: **Productos de un solo uso / *Single-use products***
Grupo genérico/ *Generic group*: **Instrumentos para punción, inyección y/o extracción de fluidos / *Instruments for puncture, 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
ROAD 31 KM. 24.3 P.O. BOX 4010 JUNCOS, PUERTO RICO 00777-4010

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

Este certificado debe ir acompañado por / *This certificate must be accompanied by*: Certificado de examen CE de tipo (Anexo III) para los productos de clase III y Declaración CE de conformidad (anexo VII) para los productos de clase IIa / *EC Type examination certificate (Annex III) for Class III medical devices and EC Declaration of conformity (Annex VII) for class IIa medical devices.*

Este certificado es consecuencia de la auditoria del sistema completo de garantía de calidad de la producción y del examen de la documentación técnica contenida en el expediente nº 95 04 0005, y garantiza que los productos descritos cumplen los requisitos de la Directiva. / *This certificate is issued on the production quality assurance system audit, and the examination of the technical documentation contained in dossier no 95 04 0005, and guarantees that the described products fulfils the requirements of the 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: K 8 K 7 X 4 B 6 A 5

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Representante autorizado ante la UE / *Authorized EU representative*: Idem

Tipo de producto / *Devices type*: Agujas espinales, introductor de agujas espinales, jeringas con y sin aguja, jeringas para insulina / *Spinal needle, needle introducer, syringes with and without needle and insulin syringes.*

Clasificación / *Classification:* III

1 Agujas espinales / *Spinal needles*

Código NANDO / NANDO code:MD 0102, MDS 7006

1.1 Agujas espinales Whitacre punta tipo lápiz / *Whitacre Pencil Point Spinal Needles* **(Descrito en el certificado de examen CE de tipo nº 2010 02 0700 ET** */ Described in the EC Type-examination certificate no 2010 02 0700 ET)*

1.1.a Aguja espinal Whitacre punta tipo lápiz estéril / *Sterile Whitacre Pencil Point Spinal Needle:* **BD Whitacre Needle**

1.1.a.1. 22G × 3.50" (0.7 × 90 mm)

1.1.a.2. 24G × 3.50" (0.55 × 90 mm)

1.1.a.3. 25G × 3.50" (0.50 × 90 mm)

1.1.a.4. 25G × 4.06" (0.50 × 103 mm)

1.1.a.5. 27G × 3.50" (0.40 × 90 mm)

1.1.a.6. 27G × 4.06" (0.40 × 103 mm)

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1.1.b Set aguja espinal Whitacre punta tipo lápiz con introductor, estéril / *Sterile Whitacre Pencil Point Spinal Needle with introducer set:* **BD Whitacre Needle**

1.1.b.1. 25G × 3.50" (0.50 × 90 mm) con introductor / *with introducer* 20G × 1.25" (0.9 × 32 mm)

1.1.b.2. 25G × 4.06" (0.50 × 103 mm) con introductor / *with introducer* 20G × 1.25" (0.9 × 32 mm)

1.1.b.3. 27G × 3.50" (0.40 × 90 mm) con introductor / *with introducer* 20G × 1.25" (0.9 × 32 mm)

1.1.b.4. 27G × 4.06" (0.40 × 103 mm) con introductor / *with introducer* 20G × 1.25" (0.9 × 32 mm)

1.2. Agujas espinales punta tipo Quincke / *Spinal needle Quincke type point (***Descrito en el certificado de examen CE de tipo nº 2010 02 0701 ET** / *Described in the EC Type-examination certificate no 2010 02 0701 ET)*

1.2.a Aguja espinal estéril punta tipo Quincke / *Sterile spinal needle Quincke type point:* **BD Spinal Needle**

1.2.a.1. 18G × 3.00" (1.2 × 75 mm)

1.2.a.2. 18G × 3.50" (1.2 × 90 mm)

1.2.a.3. 19G × 3.00" (1.1 × 75 mm)

1.2.a.4. 19G × 3.50" (1.1 × 90 mm)

1.2.a.5. 20G × 1.50" (0.90 × 38 mm)

1.2.a.6. 20G × 3.00" (0.90 × 75 mm)

1.2.a.7. 20G × 3.50" (0.90 × 90 mm)

1.2.a.8. 22G × 1.50" (0.7 × 38 mm)

1.2.a.9. 22G × 2.50" (0.7 × 63 mm)

1.2.a.10. 22G × 3.00" (0.7 × 75 mm)

1.2.a.11. 22G × 3.50" (0.7 × 90 mm)

1.2.a.12. 23G × 3.50" (0.64 × 90 mm)

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1.2.a.13. 25G × 1.00" (0.50 × 25 mm) NEONATAL

1.2.a.14. 25G × 2.00" (0.50 × 51 mm) NEONATAL

1.2.a.15. 25G × 3.00" (0.50 × 75 mm)

1.2.a.16. 25G × 3.50" (0.50 × 90 mm)

1.2.a.17. 26G × 3.50" (0.45 × 90 mm)

1.2.a.18. 27G × 3.50" (0.40 × 90 mm)

1.2.b Aguja espinal no estéril punta tipo Quincke / *Non-sterile spinal needle Quincke type point:* **BD Spinal Needle**

1.2.b.1. 22G × 3.50" (0.70 × 90 mm)

1.2.b.2. 25G × 3.50" (0.50 × 90 mm)

1.2.b.3. 26G × 3.50" (0.45 × 90 mm)

1.2.c Set aguja espinal punta tipo Quincke con introductor, estéril / *Sterile spinal needle Quincke type point with introducer set:* **BD Spinal Needle**

1.2.c.1. 25G × 3.50" (0.50 × 90 mm) con introductor / *with introducer* 20G × 1.25" (0.9 × 32 mm)

1.2.c.2. 26G × 3.50" (0.45 × 90 mm) con introductor / *with introducer* 20G × 1.25" (0.9 × 32 mm)

1.2.c.3. 27G × 3.50" (0.40 × 90 mm) con introductor / *with introducer* 20G × 1.25" (0.9 × 32 mm)

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1.3 Agujas espinales BD Whitacre NRFit™ / *BD Whitacre Spinal NRFit™ Needles*

(Descrito en el certificado de examen CE de tipo nº 2020 04 0912 ET / *Described in the EC Type-examination certificate no 2020 04 0912 ET)*

1.3.a Agujas espinales BD Whitacre NRFit™ estériles / *Sterile BD Whitacre Spinal NRFit™ Needles*

1.3.a.1 25G × 4.06" (0.50 × 103.2 mm)

1.3.a.2 25G × 4.70" (0.50 × 119.1 mm)

1.3.a.3 27G × 4.06" (0.40 × 103.2 mm)

1.3.a.4 27G × 4.70" (0.40 × 119.1 mm)

1.3.a.5 22G × 3.50" (0.70 × 88.9 mm)

1.3.a.6 24G × 3.50" (0.55 × 88.9 mm)

1.3.a.7 25G × 3.50" (0.50 × 88.9 mm)

1.3.a.8 27G × 3.50" (0.40 × 88.9 mm)

1.3.a.9 20G × 3.5" (0.90 × 88.9 mm)

1.3.a.10 21G × 3.5" (0.80 × 88.9 mm)

1.3.a.11 22G × 4" (0.70 × 101.6 mm)

1.3.a.12 26G × 3.5" (0.45 × 88.9 mm)

1.3.b Set aguja espinal BD Whitacre NRFit™ con introductor, estéril / *Sterile BD Whitacre Spinal NRFit™ Needle with introducer set.*

1.3.b.1 27G × 3.50" (0.40 × 88.9 mm) con introductor / *with introducer* 22G × 1.25" (0.70 × 31.8 mm)

1.3.b.2 25G × 3.50" (0.50 × 88.9 mm) con introductor / *with introducer* 20G × 1.25" (0.90 × 31.8 mm)

1.3.b.3 25G × 4.06" (0.50 × 103.2 mm) con introductor / *with introducer* 20G × 1.25" (0.90 × 31.8 mm)

1.3.b.4 27G × 4.06" (0.40 × 103.2 mm) con introductor / *with introducer* 22G × 1.25" (0.70 × 31.8 mm)

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1.4 Agujas espinales BD Quincke NRFit™ / *BD Quincke Spinal NRFit™ Needles*

(Descrito en el certificado de examen CE de tipo nº 2020 04 0913 ET / *Described in the EC Type-examination certificate no 2020 04 0913 ET)*

1.4.a Agujas espinales BD Quincke NRFit™ estériles / *Sterile BD Quincke Spinal NRFit™ Needles*

1.4.a.1 25G × 3.00" (0.5 × 76.2 mm)

1.4.a.2 18G × 3.00" (1.2 × 76.2 mm)

1.4.a.3 18G × 3.50" (1.2 × 88.9 mm)

1.4.a.4 22G × 1.50" (0.7 × 38.1 mm)

1.4.a.5 22G × 2.50" (0.7 × 63.5 mm)

1.4.a.6 22G × 3.00" (0.7 × 76.2 mm)

1.4.a.7 22G × 3.50" (0.7 × 88.9 mm)

1.4.a.8 25G × 1.00" (0.5 × 25.4 mm)

1.4.a.9 25G × 3.50" (0.5 × 88.9 mm)

1.4.a.10 18G × 6.00" (1.20 × 152.4 mm)

1.4.a.11 20G × 6.00" (0.90 × 152.4 mm)

1.4.a.12 22G × 5.00" (0.70 × 127 mm)

1.4.a.13 22G × 7.00" (0.70 × 177.8 mm)

1.4.a.14 25G × 4.70" (0.50 × 119.1 mm)

1.4.a.15 25G × 2.00" (0.5 × 50.8 mm)

1.4.a.16 19G × 3.00" (1.1 × 76.2 mm)

1.4.a.17 19G × 3.50" (1.1 × 88.9 mm)

1.4.a.18 20G × 1.50" (0.9 × 38.1 mm)

1.4.a.19 20G × 3.00" (0.9 × 76.2 mm)

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1.4.a.20 20G × 3.50" (0.9 × 88.9 mm)

1.4.a.21 23G × 3.50" (0.6 × 88.9 mm)

1.4.a.22 26G × 3.50" (0.45 × 88.9 mm)

1.4.a.23 27G × 3.50" (0.4 × 88.9 mm)

1.4.b Set Aguja espinal BD Quincke NRFit™ con introductor, estéril / *Sterile BD Quincke Spinal NRFit™ Needle with introducer set*

1.4.b.1 25G × 3.50" (0.50 × 88.9 mm) con introductor / *with introducer* 20G × 1.25" (0.90 × 31.8 mm)

1.4.b.2 26G × 3.50" (0.45 × 88.9 mm) con introductor / *with introducer* 22G × 1.25" (0.70 × 31.8 mm)

1.4.b.3 27G × 3.50" (0.40 × 88.9 mm) con introductor / *with introducer* 22G × 1.25" (0.70 × 31.8 mm)

Clasificación / *Classification:* IIa

2. Introductor de agujas espinales / *Needle introducer*

Código NANDO / NANDO code: MD 0102, MDS 7006

2.1. BD Introductor de agujas espinales, estéril / *Sterile BD Spinal needle introducer*

2.1.a. 20G × 1.25" (0.90 × 32 mm)
2.1.b. 22G × 1.25" (0.70 × 32 mm)

2.2 BD Aguja introductora espinal NRFit™ estéril / *Sterile BD Spinal needle introducer NRFit™*

2.3.a 20G × 1.25" (0.90 × 31.8 mm)
2.3.b 22G × 1.25" (0.70 × 31.8 mm)

2.3 BD Aguja introductora espinal NRFit™ no estéril / *Non-sterile BD Spinal needle introducer NRFit™*

2.4.a 20G × 1.25" (0.90 × 31.8 mm)
2.4.b 22G × 1.25" (0.70 × 31.8 mm)

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3. Jeringas de tres piezas con aguja / *Three-piece syringes with needle*

Código NANDO / NANDO code: MD 0102, MDS 7006

3.1. Jeringas estériles BD Plastipak™ cono Luer con aguja BD Microlance™ 3 / *Sterile BD Plastipak™ Luer-Slip syringes with BD Microlance™ 3 needle*

3.1.a. Jeringas de: / *Syringes of:* 1 ml

3.1.a.1. Con aguja / *With needle:* 25G × ⅝" (0.5 × 16 mm)

3.1.a.2. Con aguja / *With needle:* 26G × ⅜" (0.45 × 10 mm)

3.1.a.3. Con aguja / *With needle:* 23G × 1" (0.6 × 25 mm)

3.1.a.4. Con aguja / *With needle:* 22G × 1 ½" (0.7 × 40 mm)

3.1.a.5. Con aguja / *With needle:* 22G × 1 ¼" (0.7 × 30 mm)

3.1.b. Jeringas de: / *Syringes of:* 2 ml

3.1.b.1. Con aguja / *With needle*: 21G × ⅝" (0.8 × 16 mm)

3.1.b.2. Con aguja / *With needle*: 21G × 1½" (0.8 × 40 mm)

3.1.b.3. Con aguja / *With needle*: 22G × 1¼" (0.7 × 30 mm)

3.1.b.4. Con aguja / *With needle*: 23G × 1" (0.6 × 25 mm)

3.1.b.5. Con aguja / *With needle*: 25G × ⅝" (0. 5 × 16 mm)

3.1.c. Jeringas de: / *Syringes of:* 5 ml

3.1.c.1. Con aguja / *With needle*: 21G × 1½" (0.8 × 40 mm)

3.1.c.2. Con aguja / *With needle*: 22G × 1¼" (0.7 × 30 mm)

3.1.d. Jeringas de: / *Syringes of:* 10 ml

3.1.d.1. Con aguja/ *With needle*: 21G × 1½" (0.8 × 40 mm)

3.1.e. Jeringas de: / *Syringes of:* 20 ml

3.1.e.1. Con aguja / *With needle:* 21G × 1½" (0.8 × 40 mm)

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3.2. Jeringas estériles BD Plastipak™ Luer-Lok™ con aguja BD Microlance™ 3 / *Sterile BD Plastipak™ Luer-Lok™ syringes with BD Microlance™ 3 needles*

3.2.a. Jeringa de 50 ml con aguja 14G × 1¼" (2.1 × 30 mm) / *Syringes of 50 ml with 14G × 1¼" (2.1 × 30 mm) needle*

3.2.b. Jeringa de 50 ml color ámbar con aguja 14G × 1¼" (2.1 × 30 mm) / *Amber color syringes of 50 ml with 14G × 1¼" (2.1 × 30 mm) needle*

3.3. Jeringas estériles BD Plastipak™ Luer-Lok™ con aguja Blunt / *Sterile BD Plastipak™ Luer-Lok™ syringes with Blunt Fill Needle*

3.3.a. Jeringas de 50 ml con aguja 18G × 1½" (1.2 × 40 mm) / *Syringes of 50 ml with needle 18G × 1½" (1.2 × 40 mm)*

3.3.b. Jeringas de 50 ml color ámbar con aguja 18G × 1½" (1.2 × 40 mm) / *Amber color syringes of 50 ml with needle 18G × 1½" (1.2 × 40 mm)*

3.3.c. Jeringas de 50 ml con aguja 18G × 1" (1.2 × 25 mm) / *Syringes of 50 ml with Needle 18G × 1" (1.2 × 25 mm)*

3.3.d. Jeringas de 50 ml color ámbar con aguja 18G × 1" (1.2 × 25 mm) / *Amber color syringes of 50 ml with Needle 18G × 1" (1.2 × 25 mm)*

3.4. Jeringas estériles BD Perfusion con aguja BD Microlance™ 3 / *Sterile BD Perfusion syringes with BD Microlance™ 3 needle*

3.4.a. Jeringas con aguja 14G × 1¼" (2.1 × 30 mm) / *Syringes with 14G × 1¼" (2.1 × 30 mm) needle*

3.4.b. Jeringas color ámbar con aguja 14G × 1¼" (2.1 × 30 mm) / *Amber color syringes with 14G × 1¼" (2.1 × 30 mm) needle*

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4. Jeringas de tres piezas sin aguja / *Three-piece syringes without needle*

Código NANDO / NANDO code:MD 0102, MDS 7006

4.1. Jeringas estériles BD Perfusion / *Sterile BD Perfusion* syringes

4.1.a. Jeringas de / *Syringes of:* 50 ml

4.1.b. Jeringas color ambar de / *Amber color syringes of:* 50 ml

4.1.c. Envase *Convenience* de jeringas de / *Convenience Pack of syringes of:* 50 ml

4.2. Jeringas estériles BD Plastipak™ Luer-Lok™ / *Sterile BD Plastipak™ Luer-Lok™ syringes*

4.2.a. Jeringas de: / *Syringes of:* 10 ml

4.2.b. Jeringas de: / *Syringes of*: 20 ml

4.2.c. Envase *Convenience* de jeringas de: / *Convenience Pack of syringes of:* 20 ml

4.2.d. Jeringas de: / *Syringes of:* 30 ml

4.2.e. Jeringas de: / *Syringes of:* 50 ml

4.2.f. Jeringas de color ámbar: / *Amber color syringes of:* 50 ml

4.2.g. Envase *Convenience* de jeringas de: / *Convenience Pack of syringes of:* 50 ml

4.3. Jeringas no estériles BD Plastipak™ Luer-Lok™ / *Non-sterile BD Plastipak™ Luer-Lok™ syringes*

4.3.a. Jeringas de: / *Syringes of:* 20 ml

4.3.b. Jeringas de: / *Syringes of:* 50 ml

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EC PRODUCTION QUALITY ASSURANCE CERTIFICATE
in accordance with Annex V of Directive 93/42/EEC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
95 06 0005 CP	**Desde/*From***	**25-05-2020**	**Hasta/*To***	**24-05-2024**	**0318**

5. Jeringas de tres piezas cono Luer con aguja para insulina / *Three-piece insulin Luer-Slip syringes with needle*

Código NANDO / NANDO code:MD 0102, MDS 7006

5.1. Jeringas para insulina de 1 ml 40 UI / *Insulin 1ml 40 I.U. syringes*

5.1.a.1. Con aguja / *With needle*: 30G × ½″ (0.3 × 13 mm)

5.2. Jeringas para insulina de 1 ml 100 UI / *Insulin 1ml 100 I.U. syringes*

5.2.a.1. Con aguja / *With needle*: 25G × ⅝″ (0.5 × 16 mm)

5.2.a.2. Con aguja / *With needle*: 26G × ⅜″ (0.45 × 10 mm)

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

MODELO-2 ANEXO V CP Cert. 93/42/2- Rev. 18/05/2020

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

CERTIFICADO DE EXAMEN CE DE TIPO
de acuerdo con el Anexo III de la Directiva 93/42/CEE

EC TYPE-EXAMINATION CERTIFICATE
in accordance with Annex III of Directive 93/42/EEC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
2010 02 0701 ET	**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/*For the product*:

Categoría/*Category*: **Productos de un solo uso / *Single-use products***
Grupo genérico/ *Generic group*: **Instrumentos para punción, inyección y/o extracción de fluidos / *Instruments for puncture, 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
ROAD 31 KM. 24.3 P.O. BOX 4010 JUNCOS, PUERTO RICO 00777-4010

Fecha inicial / *Initial date:* 08-02-2010
Fecha de prórroga anterior / *Previous extension date:* 25-05-2015

Este certificado debe ir acompañado por un certificado de alguno de los procedimientos previstos en el art. 11 de la Directiva. / *This certificate must be accompanied by a certificate of one of the procedures foreseen in article 11 of the Directive.* / Este certificado cuya documentación técnica está contenida en el expediente nº 95 04 0005, garantiza que los productos descritos cumplen los requisitos de la Directiva. / *This certificate whose technical documentation is contained in dossier no 95 04 0005, guarantees that the described products fulfils the requirements of the 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: K 5 T R 3 Q S 9 7 5

CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

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

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO DE EXAMEN CE DE TIPO
de acuerdo con el Anexo III de la Directiva 93/42/CEE

EC TYPE-EXAMINATION CERTIFICATE
in accordance with Annex III of Directive 93/42/EEC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
2010 02 0701 ET	**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

Tipo de producto / *Devices type*: Agujas espinales / *Spinal needles*

Clasificación / *Classification:* III

Código NANDO / NANDO code: MD 0102, MDS 7006

1. Agujas espinales punta tipo Quincke / *Spinal needle Quincke type point*

1.1. Aguja espinal estéril punta tipo Quincke / *Sterile spinal needle Quincke type point:* **BD Spinal Needle**

1.1.a	18G × 3.00" (1.2 × 75 mm)
1.1.b	18G × 3.50" (1.2 × 90 mm)
1.1.c	19G × 3.00" (1.1 × 75 mm)
1.1.d	19G × 3.50" (1.1 × 90 mm)
1.1.e	20G × 1.50" (0.90 × 38 mm)
1.1.f	20G × 3.00" (0.90 × 75 mm)
1.1.g	20G × 3.50" (0.90 × 90 mm)
1.1.h	22G × 1.50" (0.7 × 38 mm)
1.1.i	22G × 2.50" (0.7 × 63 mm)
1.1.j	22G × 3.00" (0.7 × 75 mm)
1.1.k	22G × 3.50" (0.7 × 90 mm)
1.1.l	23G × 3.50" (0.64 × 90 mm)
1.1.m	25G × 1.00" (0.50 × 25 mm) NEONATAL
1.1.n	25G × 2.00" (0.50 × 51 mm) NEONATAL
1.1.o	25G × 3.00" (0.50 × 75 mm)
1.1.p	25G × 3.50" (0.50 × 90 mm)
1.1.q	26G × 3.50" (0.45 × 90 mm)
1.1.r	27G × 3.50" (0.40 × 90 mm)

CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

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

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO DE EXAMEN CE DE TIPO
de acuerdo con el Anexo III de la Directiva 93/42/CEE

EC TYPE-EXAMINATION CERTIFICATE
in accordance with Annex III of Directive 93/42/EEC

Certificado nº/*Certificate no*		Fecha de validez/*Date of validity*			ON nº/*NB no*
2010 02 0701 ET	**Desde/*From***	**25-05-2020**	**Hasta/*To***	**24-05-2024**	**0318**

1.2. Aguja espinal no estéril punta tipo Quincke / *Non-sterile spinal needle Quincke type point:* **BD Spinal Needle**

1.2.a 22G × 3.50" (0.70 × 90 mm)
1.2.b 25G × 3.50" (0.50 × 90 mm)
1.2.c 26G × 3.50" (0.45 × 90 mm)

1.3. Set aguja espinal punta tipo Quincke con introductor, estéril / *Sterile spinal needle Quincke type point with introducer set:* **BD Spinal Needle**

1.3.a 25G × 3.50" (0.50 × 90 mm) con introductor / with introducer 20G × 1.25" (0.9 × 32 mm)
1.3.b 26G × 3.50" (0.45 × 90 mm) con introductor / with introducer 20G × 1.25" (0.9 × 32 mm)
1.3.c 27G × 3.50" (0.40 × 90 mm) con introductor / with introducer 20G × 1.25" (0.9 × 32 mm)

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

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

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:

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