

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



EC DECLARATION OF CONFORMITY **DECLARACIÓN DE CONFORMIDAD CE**

Manufacturer: <i>Fabricante:</i>	Becton Dickinson S.A. Camino de Valdeoliva s/n 28750 – San Agustín del Guadalix MADRID – ESPAÑA	
Manufacturing Site(s): <i>Planta(s) de Fabricación:</i>	Becton Dickinson S.A. Camino de Valdeoliva s/n 28750 – San Agustín del Guadalix MADRID – ESPAÑA	BD Caribe Ltd. Road 31, Km 24.3 P.O. Box 4010 Juncos, Puerto Rico 00777-4010
Sterilization Site(s): <i>Planta(s) de Esterilización:</i>	Becton Dickinson S.A. Crta. Mequinenza s/n. 22520 – Fraga HUESCA – ESPAÑA	
Products: <i>Productos:</i>	BD Spinal Needles Quincke Type Point <i>Agujas Espinales BD Punta Tipo Quincke</i> See list of references attached / <i>ver listado de referencias adjunto.</i>	
Classification: <i>Clasificación:</i>	Class III as per Rule 6 of Annex IX of the Medical Devices Directive 93/42/EEC (June 14 th , 1993). <i>Clase III según la Regla 6 del Anexo IX de la Directiva de Productos Sanitarios 93/42/CEE (14 de junio de 1993).</i>	
Conformity Assessment Route: <i>Procedimiento de evaluación de la conformidad:</i>	Annexes III and V <i>Anexos III y V</i>	
GMDN:	GMDN Code / Código: 35212 GMDN Term / Término: Single use spinal anesthesia needle / <i>Aguja espinal para anestesia de un solo uso</i>	

We hereby declare that the products mentioned above meet the provisions of the Council Directive 93/42/EEC of June 14th, 1993 concerning medical devices. This declaration of conformity is issued under the sole responsibility of the manufacturer. All supporting documentation is retained at the premises of the manufacturer.

Por la presente declaramos que los productos antes mencionados cumplen las disposiciones de la Directiva 93/42/EEC de 14 de junio de 1993 sobre productos sanitarios. La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante. Toda la documentación de soporte se guarda en las instalaciones del fabricante.

List of Harmonized Standards: <i>Lista de Normas Armonizadas:</i>	EN 556-1:2024, EN ISO 15223-1:2021, EN ISO 10993 series, EN ISO 11737-2:2020, EN ISO 13485:2016/A11:2021
Non-Harmonized standards: <i>Normas No Armonizadas:</i>	EN ISO 9626:2016, EN ISO 6009:2016, EN ISO 10993-10:2023, EN ISO 11135:2014/A1:2019, EN ISO 20417:2021, EN ISO 11138-2:2017, EN ISO 11737-1:2018/A1:2021, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14971:2019
Notified Body: <i>Organismo Notificado:</i>	Agencia Española de Medicamentos y Productos Sanitarios Parque Empresarial Las Mercedes. Edificio 8 Calle Campezo, 1 28022 – MADRID Notified Body Number / <i>Número del Organismo Notificado:</i> 0318
EC Certificate Number: <i>Número certificado CE:</i>	Annex V / <i>Anexo V:</i> 95 06 0005 CP Annex III / <i>Anexo III:</i> 2010 02 0701 ET
Date of issuance of the original CE Mark: <i>Inicio de la marca CE:</i>	Initial Date: June 19 th , 1995 <i>Fecha inicial: 19 de junio de 1995</i>

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

Elena Morollón

Regulatory Affairs Sr. Manager
Becton Dickinson S.A.

Signature / Firma: _____

DocuSigned by:

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PRODUCT LIST
LISTA DE PRODUCTOS

STERILE BD SPINAL NEEDLE QUINCKE TYPE POINT
AGUJA ESPINAL BD ESTÉRIL PUNTA TIPO QUINCKE

Reference <i>Referencia</i>	Description <i>Descripción</i>
405244	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 22G × 2.50" (0.7 × 63 mm)
405246	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 25G × 3.00" (0.50 × 75 mm)
405247	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 18G × 3.00" (1.2 × 75 mm)
405248	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 18G × 3.50" (1.2 × 90 mm)
405249	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 19G × 3.00" (1.1 × 75 mm)
405250	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 19G × 3.50" (1.1 × 90 mm)
405251	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 20G × 1.50" (0.90 × 38 mm)
405252	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 20G × 3.00" (0.90 × 75 mm)
405253	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 20G × 3.50" (0.90 × 90 mm)
405254	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 22G × 1.50" (0.7 × 38 mm)
405255	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 22G × 3.00" (0.7 × 75 mm)
405256	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 22G × 3.50" (0.7 × 90 mm)
405257	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 25G × 3.50" (0.50 × 90 mm)
405258	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 26G × 3.50" (0.45 × 90 mm)
405259	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 27G × 3.50" (0.40 × 90 mm)
405240	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 23G × 3.50" (0.64 × 90 mm)

NEONATAL BD SPINAL NEEDLES
AGUJAS ESPINALES BD NEONATALES

Reference <i>Referencia</i>	Description <i>Descripción</i>
405243	BD Neonatal Spinal Needle Quincke Type Point <i>Aguja Espinal BD Neonatal Punta Tipo Quincke</i> 25G × 1.00" (0.50 × 25 mm)
405245	BD Neonatal Spinal Needle Quincke Type Point <i>Aguja Espinal BD Neonatal Punta Tipo Quincke</i> 25G × 2.00" (0.50 × 51 mm)

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STERILE BD SPINAL NEEDLE QUINCKE TYPE POINT WITH INTRODUCER SET
SET AGUJA ESPINAL BD PUNTA TIPO QUINCKE CON INTRODUCTOR, ESTÉRIL

Reference <i>Referencia</i>	Description <i>Descripción</i>
405084	BD Spinal Needle Set Quincke Type Point <i>Set Aguja Espinal BD Punta Tipo Quincke</i> 25G × 3.50" (0.50 × 90 mm) + 20G 1.25" (0.9 × 32 mm)
405065	BD Spinal Needle Set Quincke Type Point <i>Set Aguja Espinal BD Punta Tipo Quincke</i> 26G × 3.50" (0.45 × 90 mm) + 20G 1.25" (0.9 × 32 mm)
405069	BD Spinal Needle Set Quincke Type Point <i>Set Aguja Espinal BD Punta Tipo Quincke</i> 27G × 3.50" (0.40 × 90 mm) + 22G 1.25" (0.7 × 32 mm)

PRODUCTS FOR INDIA
PRODUCTOS PARA INDIA

Reference <i>Referencia</i>	Description <i>Descripción</i>
405125	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 18G × 3.50" (1.20 × 90 mm)
405123	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 20G × 3.50" (0.90 × 90 mm)
405121	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 22G × 3.50" (0.70 × 90 mm)
405120	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 23G × 3.50" (0.64 × 90 mm)
405122	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 25G × 3.50" (0.50 × 90 mm)
405124	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 26G × 3.50" (0.45 × 90 mm)
405127	BD Spinal Needle Quincke Type Point <i>Aguja Espinal BD Punta Tipo Quincke</i> 27G × 3.50" (0.40 × 90 mm)
405126	BD Spinal Needle Set Quincke Type Point <i>Set Aguja Espinal BD Punta Tipo Quincke</i> 27G × 3.50" (0.40 × 90 mm) + 22G 1.25" (0.7 × 32 mm)

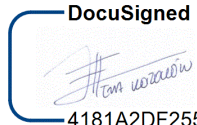
Under Art. 120 (3) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 amended by Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 the responsibility of surveillance of certificates 95 06 0005 CP and 2010 02 0701 ET has been transferred to BSI (2797) which has issued certificates AR120 818297 and AR120 818312 on January 10, 2025.

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