

EC DECLARATION OF CONFORMITY
DECLARACIÓN CE DE CONFORMIDAD

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| Manufacturer <i>Fabricante</i> | Becton Dickinson S.A. Camino de Valdeoliva, s/n 28750 – San Agustin del Guadalix (Madrid) - SPAIN | |
| Authorised Representative <i>Representante Autorizado</i> | Not applicable <i>No aplicable</i> | |
| Manufacturing Site <i>Planta de Fabricación</i> | Becton Dickinson S.A. Camino de Valdeoliva, s/n 28750 – San Agustin del Guadalix (Madrid) - SPAIN | BD Caribe, LTD Road 31 Km 24,3 P.O. BOX 4010 Juncos Puerto Rico 00777-4010 |
| 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 according to the Rule 6 of the Annex IX of the 93/42/EEC Medical Devices Directive. <i>Clase III, de acuerdo con la Regla 6 del Anexo IX de la Directiva de Productos Sanitarios 93/42/EEC.</i> | |
| Conformity Assessment Route <i>Procedimiento de evaluación de la conformidad</i> | Annexes III and V <i>Anexos III y V</i> | |

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices. All supporting documentation is retained under 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 mantiene en las instalaciones del fabricante.

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| List of Harmonized standards <i>Lista de Normas Armonizadas</i> | EN 556-1, EN 980, EN 1041, EN 1707, EN ISO 10993 series, EN ISO 11135-1, EN ISO 11138-2, EN ISO 13485, EN ISO 14155, EN ISO 14971, EN ISO 11607-1, EN ISO 11607-2, EN ISO 11737-1, EN ISO 11737-2, EN 20594-1 |
| 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> : N° 95 06 0005CP Annex III/ <i>Anexo III</i> : N° 2010 02 0701ET |
| Start of CE marking <i>Inicio de la marca CE</i> | <i>June 19, 1995</i> <i>19 de Junio de 1995</i> |

Date: March 7, 2014
Fecha: 7 de marzo de 2014

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 JOSE LUIS GÓMEZ RUIZ
 General Director – Becton Dickinson S.A.
Director General – Becton Dickinson S. A.

Annex
 Anexo

Sterile BD Spinal Needles
Agujas Espinales BD Estériles

| Ref. # | Description/ Descripción | |
|--------|---|----------------------------|
| 405247 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 18 GA 3.00 IN 1.20 x 75 mm |
| 405248 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 18 GA 3.50 IN 1.20 x 90 mm |
| 405249 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 19 GA 3.00 IN 1.10 x 75 mm |
| 405250 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 19 GA 3.50 IN 1.10 x 90 mm |
| 405251 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 20 GA 1.50 IN 0.90 x 38 mm |
| 405252 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 20 GA 3.00 IN 0.90 x 75 mm |
| 405253 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 20 GA 3.50 IN 0.90 x 90 mm |
| 405254 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 22 GA 1.50 IN 0.70 x 38 mm |
| 405244 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 22 GA 2.50 IN 0.70 x 63 mm |
| 405255 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 22 GA 3.00 IN 0.70 x 75 mm |
| 405256 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 22 GA 3.50 IN 0.70 x 90 mm |
| 405240 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 23 GA 3.50 IN 0.64 x 90 mm |
| 405246 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 25 GA 3.00 IN 0.50 x 75 mm |
| 405257 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 25 GA 3.50 IN 0.50 x 90 mm |
| 405258 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 26 GA 3.50 IN 0.45 x 90 mm |
| 405259 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 27 GA 3.50 IN 0.40 x 90 mm |
| 405243 | BD Neonatal Spinal Needle/ <i>Aguja Espinal Neonatal BD</i> | 25 GA 1.00 IN 0.50 x 25 mm |
| 405245 | BD Neonatal Spinal Needle/ <i>Aguja Espinal Neonatal BD</i> | 25 GA 2.00 IN 0.50 x 51 mm |
| 405084 | BD Spinal Needle with Introducer/ <i>Aguja Espinal BD con Introducitor</i> | 25GA 3.50 IN 0.50 x 90 mm |
| 405065 | BD Spinal Needle with Introducer/ <i>Aguja Espinal BD con Introducitor</i> | 26GA 3.50 IN 0.45 x 90 mm |
| 405069 | BD Spinal Needle with Introducer/ <i>Aguja Espinal BD con Introducitor</i> | 27GA 3.50 IN 0.40 x 90 mm |
| 405068 | BD Spinal Needle with Introducer/ <i>Aguja Espinal BD con Introducitor</i> | 29GA 3.50 IN 0.33 x 90 mm |

References for Indian market/ *Referencias para el mercado indio*

| Ref. # | Description/ Descripción | |
|--------|---|----------------------------|
| 405125 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 18 GA 3.50 IN 1.20 x 90 mm |
| 405123 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 20 GA 3.50 IN 0.90 x 90 mm |
| 405121 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 22 GA 3.50 IN 0.70 x 90 mm |
| 405120 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 23 GA 3.50 IN 0.64 x 90 mm |
| 405122 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 25 GA 3.50 IN 0.50 x 90 mm |
| 405124 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 26 GA 3.50 IN 0.45 x 90 mm |
| 405127 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> | 27 GA 3.50 IN 0.40 x 90 mm |
| 405126 | BD Spinal Needle with Introducer/ <i>Aguja Espinal BD con Introducitor</i> | 27GA 3.50 IN 0.40 x 90 mm |

Non Sterile BD Spinal Needles
Agujas Espinales BD No Estériles

| Ref. # | Description/ Descripción |
|--------|--|
| 400497 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> 22 GA 3.50 IN 0.70 x 90 mm |
| 400496 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> 25 GA 3.50 IN 0.50 x 90 mm |
| 400476 | BD Spinal Needle Quincke Type Point/ <i>Aguja Espinal BD punta tipo Quincke</i> 26 GA 3.50 IN 0.45 x 90 mm |

