

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

Legal Manufacturer: <i>Fabricante Legal:</i>	Becton Dickinson S.A. Camino de Valdeoliva, s/n 28750 – San Agustin del Guadalix (Madrid) - SPAIN	
Manufacturing Site (s): <i>Planta(s) 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>	
GMDN	GMDN code/código 35212 GMDN term / termino: Spinal anesthesia needle. Single use / Aguja espinal para anestesia. Un solo uso	

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.*

Harmonized standards <i>Normas Armonizadas</i>	EN 556-1:2001/AC:2006, EN 980:2008, EN 1041:2008+A1:2013, EN ISO 10993 series, EN ISO 11135-1:2007, EN ISO 11138-2:2009, EN ISO 13485:2012/AC:2012, EN ISO 14971:2012, EN ISO 11607-1:2009/A1:2014, EN ISO 11607-2:2006/A1:2014, EN ISO 11737-1:2009, EN ISO 11737-2:2009, EN 20594-1:1993/AC:1996/A1:1997, EN 1707:1996
Non-Harmonized standards: <i>Normas No-Armonizadas:</i>	EN ISO 15223-1:2012, EN ISO 9626:1995/A1:2001
Notified Body: <i>Organismo Notificado:</i>	Agencia Española de Medicamentos y Productos Sanitarios Parque Empresarial Las Mercedes, 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
Date of issuance of the original CE certificate: <i>Fecha inicial emision certificado CE :</i>	<i>Initial date: June 19, 1995</i> <i>Fecha inicial: 19 de Junio de 1995</i>
Sterilization site: <i>Planta de esterilización:</i>	Becton Dickinson, S.A. Carretera de Mequinenza, s/n 22520 Fraga, Huesca, SPAIN

Date: May 6, 2016  
*Fecha: 6 de mayo de 2016*

JOSE LUIS GOMEZ 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 Introducutor</i> 25GA 3.50 IN 0.50 x 90 mm
405065	BD Spinal Needle with Introducer/ <i>Aguja Espinal BD con Introducutor</i> 26GA 3.50 IN 0.45 x 90 mm
405069	BD Spinal Needle with Introducer/ <i>Aguja Espinal BD con Introducutor</i> 27GA 3.50 IN 0.40 x 90 mm
405068	BD Spinal Needle with Introducer/ <i>Aguja Espinal BD con Introducutor</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 Introducutor</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

