

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

