

EC DECLARATION OF CONFORMITY
DECLARACIÓN DE CONFORMIDAD CE

Manufacturer: <i>Fabricante:</i>	Becton Dickinson S.A. Crta. Mequinenza s/n. 22520 - Fraga HUESCA – ESPAÑA
Manufacturing Site(s): <i>Planta(s) de Fabricación:</i>	Becton Dickinson S.A. Crta. Mequinenza s/n. 22520 - Fraga HUESCA – ESPAÑA
Products: <i>Productos:</i>	BD Emerald™ Syringes with needle <i>Jeringas BD Emerald™ con aguja</i>
Classification: <i>Clasificación:</i>	Class IIa, per Rule 6 of Annex IX of the Medical Devices Directive 93/42/EEC (14 th June 1993). <i>Clase IIa, 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 V and VII <i>Anexos V y VII</i>
GMDN:	47017

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 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. Toda la documentación de soporte se mantiene en las instalaciones del fabricante.

List of Harmonised Standards: <i>Lista de Normas Armonizadas:</i>	EN 556-1: 2001, EN 980: 2008, EN 1041:2008, EN ISO 10993 series, EN ISO 11135-1: 2007, EN ISO 11138-2: 2009, EN ISO 11607-1: 2009, EN ISO 11607-2: 2006, EN ISO 11737-1: 2006, EN 11737-2: 2009, EN ISO 13485: 2012, EN ISO 14971: 2012, EN 20594-1: 1993
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>	95 06 0006 CP
Date of issuance of the original CE certificate <i>Inicio de la marca CE:</i>	Initial Date: 16 th February 2011 <i>Fecha inicial: 16 de febrero de 2011</i>

Date: June 3, 2015
Fecha: 3 de junio de 2015

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

PRODUCT LIST
LISTA DE PRODUCTOS

3 PIECES SYRINGES WITH DETACHED NEEDLE / JERINGAS DE 3 PIEZAS CON AGUJA AL LADO

Reference Referencia	Description Descripción
307729	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 23G x 1"
307730	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 23G x 1 ¼"
303119	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 21G x 1 ½"
303124	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 22G x 1 ¼"
307742	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 21G x 1 ½"
307743	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 22G x 1 ¼"
307734	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 22G x 1 ½"
307739	BD Emerald™ 10ml Syringe / Jeringa 10ml BD Emerald™ 21G x 1 ½"

3 PIECES SYRINGES WITH DETACHED NEEDLE FOR INDIA / JERINGAS DE 3 PIEZAS CON AGUJA AL LADO PARA INDIA

Reference Referencia	Description Descripción
303068	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 22G x 1"
303069	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 23G x 1"
303070	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 24G x 1"
303071	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 25G x 1"
303078	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 22G x 1"
303079	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 23G x 1"
303080	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 24G x 1"
303082	BD Emerald™ 10ml Syringe / Jeringa 10ml BD Emerald™ 21G x 1"
303083	BD Emerald™ 10ml Syringe / Jeringa 10ml BD Emerald™ 21G x 1 ½"

3 PIECES SYRINGES WITH NEEDLE ATTACHED / JERINGAS DE 3 PIEZAS CON AGUJA PREACOPLADA

Reference Referencia	Description Descripción
307728	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 22G x 1 ¼"
307740	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 23G x 1"
307741	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 23G x 1 ¼"
307732	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 21G x 1 ½"
307733	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 22G x 1 ¼"
307735	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 23G x 1 ¼"
307737	BD Emerald™ 10ml Syringe / Jeringa 10ml BD Emerald™ 21G x 1 ½"
307738	BD Emerald™ 10ml Syringe / Jeringa 10ml BD Emerald™ 22G x 1 ½"

**3 PIECES SYRINGES WITH NEEDLE ATTACHED CIS COUNTRIES / JERINGAS 3 PIEZAS CON AGUJA PREACOPADA
 PAÍSES CIS**

Reference Referencia	Description Descripción
307760	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 23G x 1"
307761	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 23G x 1 ¼"
307762	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 21G x 1 ½"
307763	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 22G x 1 ¼"
307764	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 22G x 1 ½"
307765	BD Emerald™ 10ml Syringe / Jeringa 10ml BD Emerald™ 21G x 1 ½"

**3 PIECES SYRINGES WITH NEEDLE ATTACHED, TEN PACK / JERINGAS DE 3 PIEZAS CON AGUJA PREACOPADA, TEN
 PACK**

Reference Referencia	Description Descripción
TEN PACK FOR ITALY/ TEN PACK PARA ITALIA	
302909	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 23G x 1 ¼"
302910	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 23G x 1 ¼"
TEN PACK FOR FRANCE/ TEN PACK PARA FRANCIA	
303032	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 25G x 5/8"
303034	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 23G x 1"
303044	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 21G x 1 ½"
303047	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 22G x 1 ¼"
303048	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 21G x 1 ½"
303049	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 22G x 1 ¼"
TEN PACK FOR SPAIN/ TEN PACK PARA ESPAÑA	
303112	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 23G x 1"
303113	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 25G x 5/8"
303114	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 21G x 1 ½"
303115	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 22G x 1 ¼"
TEN PACK FOR BELGIUM/ TEN PACK PARA BÉLGICA	
303109	BD Emerald™ 2ml Syringe / Jeringa 2ml BD Emerald™ 21G x 1 ½"
303111	BD Emerald™ 5ml Syringe / Jeringa 5ml BD Emerald™ 21G x 1 ½"

