

Becton Dickinson S.A.  
Ctra. Mequinenza, s/n  
22520 Fraga, Huesca, Spain  
Phone / Tlf.: +34 974470900  
Fax: +34 974470546



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

|                                                                                              |                                                                                                                                                                                                                                             |
|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Legal Manufacturer:</b><br><i>Fabricante legal:</i>                                       | Becton Dickinson S.A.<br>Ctra. Mequinenza, s/n<br>22520 – Fraga<br>HUESCA – ESPAÑA                                                                                                                                                          |
| <b>Manufacturing Site(s):</b><br><i>Planta(s) de Fabricación:</i>                            | Becton Dickinson S.A.<br>Ctra. Mequinenza, s/n<br>22520 – Fraga<br>HUESCA – ESPAÑA                                                                                                                                                          |
| <b>Sterilization Site(s):</b><br><i>Planta(s) de Esterilización:</i>                         | Becton Dickinson S.A.<br>Ctra. Mequinenza, s/n<br>22520 – Fraga<br>HUESCA – ESPAÑA                                                                                                                                                          |
| <b>Products:</b><br><i>Productos:</i>                                                        | BD Microlance™ 3 needles<br><i>Agujas BD Microlance™ 3</i><br><br>See list of references attached / <i>ver listado de referencias adjunto.</i>                                                                                              |
| <b>Classification:</b><br><i>Clasificación:</i>                                              | Class IIa, as per Rule 6 of Annex IX of the Medical Devices Directive 93/42/EEC (June 14 <sup>th</sup> , 1993).<br><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> |
| <b>Conformity Assessment Route:</b><br><i>Procedimiento de evaluación de la conformidad:</i> | Annexes V and VII<br><i>Anexos V y VII</i>                                                                                                                                                                                                  |
| <b>GMDN:</b>                                                                                 | GMDN Code / Código: 59230<br>GMDN Term / Término: 59230 Hypodermic needle, single-use / <i>aguja hipodérmica, 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 14<sup>th</sup>, 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 guarda en las instalaciones del fabricante.*

|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                              |
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| <b>List of Harmonized Standards:</b><br><i>Lista de Normas Armonizadas:</i>       | EN 556-1:2001/AC:2006, EN ISO 10993 Series, EN ISO 11737-2:2019, EN ISO 13485:2016/AC:2018, EN ISO 15223-1:2016                                                                                                                                                                                                                                                                              |
| <b>Non-Harmonized standards:</b><br><i>Normas No Armonizadas:</i>                 | EN ISO 6009:2016, EN ISO 7864:2016, EN ISO 9626:2016, EN ISO 10993-10:2013, EN 1041:2008+A1:2013, UNE-EN ISO 11135:2015, EN ISO 11737-1:2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14971:2019, UNE-EN ISO 80369-7:2022                                                                                                                                                           |
| <b>Notified Body:</b><br><i>Organismo Notificado:</i>                             | Agencia Española de Medicamentos y Productos Sanitarios<br>Parque Empresarial Las Mercedes. Edificio 8<br>Calle Campezo, 1<br>28022 – MADRID<br>Notified Body Number / <i>Número del Organismo Notificado:</i> 0318                                                                                                                                                                          |
| <b>EC Certificate Number:</b><br><i>Número certificado CE:</i>                    | 95 06 0006 CP                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Date of issuance of the original CE Mark:</b><br><i>Inicio de la marca CE:</i> | Initial Date: June 19 <sup>th</sup> , 1995<br><i>Fecha inicial: 19 de junio de 1995</i><br><br><i>CE mark for the references 303262, 303273, 303301, 310205: May 13th, 2021 / marcado CE para las referencias: 303262, 303273, 303301, 310205: 13 de mayo de 2021</i><br><i>CE mark for the reference 310208, March 14th 2022, marcado CE para la referencia 310208: 14 de marzo de 2022</i> |

Date / Fecha: September 1, 2023 / 1 de septiembre de 2023

Lourdes López  
General Director / Directora General  
Becton Dickinson S.A.

Signature / Firma: \_\_\_\_\_

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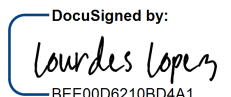
**PRODUCT LIST**  
**LISTA DE PRODUCTOS**

**STERILE NEEDLES**  
**AGUJAS ESTÉRILES**

| Reference<br>Referencia | Description<br>Descripción                                                                      |
|-------------------------|-------------------------------------------------------------------------------------------------|
| 300094                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 22G × 2" (0.7 × 50 mm)  |
| 300300                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 26G × ¾" (0.45 × 10 mm) |
| 300400                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 25G × 1" (0.5 × 25 mm)  |
| 300600                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 25G × ⅝" (0.5 × 16 mm)  |
| 300635                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 27G × ½" (0.4 × 13 mm)  |
| 300637                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 16G × 1½" (1.6 × 40 mm) |
| 300700                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 23G × 1¼" (0.6 × 30 mm) |
| 300800                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 23G × 1" (0.6 × 25 mm)  |
| 300900                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 22G × 1¼" (0.7 × 30 mm) |
| 301000                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 22G × 1½" (0.7 × 40 mm) |
| 301155                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 21G × 2" (0.8 × 50 mm)  |
| 301156                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 21G × 1" (0.8 × 25 mm)  |
| 301300                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 20G × 1½" (0.9 × 40 mm) |
| 301500                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 19G × 1½" (1.1 × 40 mm) |
| 301700                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 19G × 1" (1.1 × 25 mm)  |
| 301750                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 19G × 2" (1.1 × 50 mm)  |
| 301900                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 18G × 2" (1.2 × 50 mm)  |
| 302200                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 27G × ¾" (0.4 × 19 mm)  |
| 302809                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 30G × ½" (0.3 × 13 mm)  |
| 303800                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 26G × ½" (0.45 × 13 mm) |
| 304000                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 30G × ½" (0.3 × 13 mm)  |
| 304100                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 24G × 1" (0.55 × 25 mm) |
| 304300                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 26G × ⅝" (0.45 × 16 mm) |
| 304432                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 21G × 1½" (0.8 × 40 mm) |
| 304434                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 21G × ⅝" (0.8 × 16 mm)  |
| 304622                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 18G × 1½" (1.2 × 40 mm) |
| 304727                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 22G × 1" (0.7 × 25 mm)  |
| 304827                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 20G × 1" (0.9 × 25 mm)  |
| 303262                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 18G × 1½" (1.2 × 40 mm) |
| 303273                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 23G × 1½" (0.6 × 40 mm) |
| 310205                  | BD Microlance™ 3 Hypodermic Needle / Aguja hipodérmica BD Microlance™ 3 18G × 2" (1.2 × 50 mm)  |

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**NON-STERILE NEEDLES**  
**AGUJAS NO ESTÉRILES**

| <b>Reference</b><br><i>Referencia</i> | <b>Description</b><br><i>Descripción</i>                                                                |
|---------------------------------------|---------------------------------------------------------------------------------------------------------|
| 300403                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 25G × 1" (0.5 × 25 mm)   |
| 300802                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 21G × 1½" (0.8 × 40 mm)  |
| 300808                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 20G × 1½" (0.9 × 40 mm)  |
| 300901                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 22G × 1¼" (0.7 × 30 mm)  |
| 300932                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 30G × ½" (0.3 × 13 mm)   |
| 301296                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 27G × ½" (0.4 × 13 mm)   |
| 301530                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 19G × 1½" (1.1 × 40 mm)  |
| 303803                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 26G × ½" (0.45 × 13 mm)  |
| 304627                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 23G × 1" (0.6 × 25 mm)   |
| 304630                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 21G × 2" (0.8 × 50 mm)   |
| 304636                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 18G × 2" (1.2 × 50 mm)   |
| 304637                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 27G × ¾" (0.4 × 19 mm)   |
| 304641                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 24G × 1" (0.55 × 25 mm)  |
| 304644                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 18G × 1½" (1.2 × 40 mm)  |
| 304728                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 22G × 1" (0.7 × 25 mm)   |
| 304729                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 22G × 1½" (0.7 × 40 mm)  |
| 305146                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 23G × 1¼" (0.6 × 30 mm)  |
| 306030                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 25G × ⅝" (0.5 × 16 mm)   |
| 300806                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 21G × 1" (0.8 × 25 mm)   |
| 303301                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 18G × 2" (1.2 × 50 mm)   |
| 310208                                | BD Microlance™ 3 Hypodermic Needle / <i>Aguja hipodérmica</i> BD Microlance™ 3 27G × 3/8" (0.4 × 40 mm) |

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