



BD Medical, Diabetes Care  
 1 Becton Drive  
 Franklin Lakes  
 New Jersey 07417  
 USA  
 Tel: (201) 847-6459  
 Fax: (201) 847-4856  
[www.bd.com](http://www.bd.com)

BD Medical-Diabetes Care  
 11 rue Aristide Bergès  
 ZI des Iles – BP4  
 38801 Le Pont de Claix Cedex  
 France  
 Tel: +33 (0)4.76.68.36.36  
 Fax: +33 (0)4.76.68.34.73  
[www.bd.com](http://www.bd.com)

**EC DECLARATION OF CONFORMITY**

<b>Legal manufacturer:</b>	Becton Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417, USA
<b>Authorised Representative:</b>	BD Medical – Diabetes Care Becton Dickinson France S.A.S. 11 rue Aristide Bergès, BP 4 38801 Le Pont-de-Claix, Cedex, France
<b>Manufacturing Site:</b>	BD Medical Diabetes Care 1329 West Highway 6, Holdrege, NE 68949, USA
<b>Products:</b>	<p><b>BD Micro-Fine™ +, Micro-Fine™ Plus, Micro-Fine™, Micro-Fine™ IV, Ultra-Fine™ and Ultra-Fine™ II Insulin Syringes and Plastipak™ Syringes</b> existing in the following presentations:</p> <p><u>Plastipak™ Syringes:</u></p> <ul style="list-style-type: none"> <li>▪ 1ml Plastipak™ Syringe, 26Gx12,7mm: REF 305501, 471488, 471329</li> <li>▪ 1ml Plastipak™ Syringe, 27G x12,7mm: REF 471492, 324701</li> <li>▪ 1ml Plastipak™ Syringe, 27Gx10mm: REF 305502</li> </ul> <p><u>Insulin Syringes:</u></p> <ul style="list-style-type: none"> <li>▪ 1ml U40, 29Gx12,7mm: REF 320801, 320910</li> <li>▪ 1ml U40, 30Gx8mm: REF320911</li> <li>▪ 1ml U100, 27G x12,7mm: REF 328415</li> <li>▪ 1ml U100, 29Gx12,7mm : REF 320841, 320909, 320924, 324883, 324891, 320931, 324827, 326110, 326719</li> <li>▪ 1ml U100, 30Gx8mm: REF 320929, 324899, 320935, 326702</li> <li>▪ 1ml U100, 31Gx8mm: REF 328820</li> <li>▪ 1 ml U100, 31Gx6mm: REF 324903, 324905, 326674, 324924</li> <li>▪ 0,5ml U40, 30Gx 8mm: REF 324876</li> <li>▪ 0,5ml U100, 29Gx12,7mm: REF 320921, 320926, 324882, 324892, 324824, 326769, 326105</li> <li>▪ 0,5ml U100, 30Gx8mm: REF 320843, 320927, 320930, 324881, 324893, 320933, 324825, 326725</li> <li>▪ 0,5ml U100, 31Gx8mm: REF 328821</li> <li>▪ 0,5ml U100, 31Gx6mm: REF 324901, 324904, 326675, 324923</li> <li>▪ 0,3ml U100, 29Gx12,7mm: REF 326103</li> <li>▪ 0,3 ml U100, 30Gx 8mm (½ unit scale): REF 320829, 320839, 320840, 324826, 324922</li> <li>▪ 0,3 ml U100, 31Gx 8mm: REF 328822</li> <li>▪ 0,3 ml U100, 31G x 6mm: REF 324900</li> </ul>
<b>Classification:</b>	Ila
<b>Conformity Assessment Route:</b>	Annex V and Annex VII
<b>GMDN:</b>	<p><u>Insulin Syringes:</u> 38501 – Insulin syringe, fixed-needle</p> <p><u>Plastipak™ Syringes:</u> 35904 – Metered-delivery hypodermic syringe</p>

**TITLE: Declaration of Conformity for BD Insulin Syringes and BD Plastipak™ Syringes**

**TYPE: ZRF**

**Revision: H**

**Page 2 of 2**

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.

<b>Harmonised Standards:</b>	EN 556-1:2001/AC:2006, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 10993 series, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006/AC:2009, EN ISO 11737-2:2009, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 22442-1:2007, EN 62366:2008
<b>Non-Harmonised Standards:</b>	ISO 8537:2016, ISO 7864:1993, ISO 7886-1:1993/COR 1:1995, ISO 9626:1991/Amd.1:2001, ISO 2859-1:1999, EN ISO 11137-3: 2017
<b>Notified Body:</b>	NSAI (National Standards Authority of Ireland) 1 Swift Square, Northwood, Santry, Dublin 9, Ireland  Notified Body Number : 0050
<b>CE Certificate Number:</b>	252.140
<b>Date of issuance of the original CE certificate:</b>	7 April 1995

Date: *August 2, 2019*



.....  
Aurélie Chaudier  
Regulatory Affairs Manager  
BD Medical – Diabetes Care, EU

Date: *6 Aug 2019*



.....  
Mark O'Donnell  
Vice President – Regulatory Affairs  
BD Medical – Diabetes Care, US