

**TITLE: EC Declaration of Conformity for BD Pen Needles**



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, New Jersey 07417, USA
<b>Authorized 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 Sites:</b>	<ul style="list-style-type: none"> <li>• Becton Dickinson and Company Pottery Road – Dun Laoghaire – Co. Dublin – Ireland</li> <li>• Becton Dickinson and Company Limited Donore Road – Drogheda – Co Louth – Ireland</li> <li>• BD Medical – Diabetes Care 1329 West Highway 6 – Holdrege – NE 68949 – USA</li> <li>• Becton Dickinson Medical (S) Pte Ltd. 30 Tuas Avenue 2 – Singapore- Singapore 639461</li> <li>• Becton Dickinson Medical Devices Co., Ltd. Suzhou No 1 Liangpu Street – Suzhou Industrial Park – Jiangsu, P.R. China</li> </ul>
<b>Products:</b>	<p><b>BD™, BD Micro-Fine™, BD Micro-Fine™ +, BD Micro-Fine™ Plus, BD Micro-Fine Ultra™, BD Micro-Fine Ultra™ PRO, BD Ultra-Fine™, BD Ultra-Fine™ PRO, BD Viva™, BerliFine® Micro and Accu-Fine® Pen Needles</b> existing in the following presentations:</p> <ul style="list-style-type: none"> <li>• <u>0.33mm (29G) x 12.7mm</u>: 320117, 320167, 320180, 320188, 320189, 320207, 320216, 320304, 320473, 320516, 320630, 320633, 320652, 320672, 320690, 320790, 325118, 47250082, 47286482, 47338782, 47362282, 47530082</li> <li>• <u>0.30mm (30G) x 8mm</u>: 320164, 320190, 320190-14, 320214, 320305, 320474, 320474-14, 320517, 320519, 320591, 320653, 320691, 320692</li> <li>• <u>0.25mm (31G) x 8mm</u>: 320124, 320213, 320423, 320455, 320471, 320499, 320510, 320524, 320563, 320592, 320593, 320631, 320631-14, 320634, 320648, 320651, 320654, 320663, 320674, 320686, 320792, 320694, 320695, 325108, 325117</li> <li>• <u>0.25mm (31G) x 6mm</u>: 320523, 320655, 320675, 320687, 320733, 320734, 320736, 320737, 320739, 320743</li> </ul>

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<b>Products (continued):</b>	<ul style="list-style-type: none"> <li>• <u>0,25mm (31G) x 5mm</u>: 320120, 320130, 320165, 320165-15, 320212, 320408, 320424, 320433*, 320470, 320498, 320518, 320522, 320535, 320545*, 320569, 320590, 320594, 320595, 320632, 320632-14, 320632-15, 320632-17, 320635, 320647, 320650, 320657, 320659, 320666, 320677, 320684, 320693, 320794, 325107</li> <li>• <u>0,23mm (32G) x 6mm</u>: 320656, 320676, 320683</li> <li>• <u>0,23mm (32G) x 4mm</u>: 320157, 320177, 320137, 320138, 320139, 320140, 320141, 320142, 320143, 320177-14, 320177-15, 320177-17, 320211, 320404, 320404-14, 320404-15, 320404-17, 320405, 320407, 320425, 320426, 320434*, 320435*, 320472, 320475, 320475-14, 320475-15, 320475-17, 320476, 320477, 320497, 320500, 320520, 320561, 320562, 320564, 320566, 320571, 320636, 320646, 320649, 320658, 320660, 320667, 320678, 320685, 325103, 325106, 325115</li> <li>• <u>0,6mm (23G) x 7mm</u>: 47364902</li> </ul>
<b>Classification:</b>	Ila, Annex IX, Rule 6
<b>Conformity Assessment Route:</b>	Annex V and Annex VII
<b>GMDN</b>	<ul style="list-style-type: none"> <li>• GMDN code: 44127</li> <li>• GMDN term: Autoinjector needle</li> </ul>

\* The CE mark is affixed to the labeling of these product references from implementation of below ECOs:


- ECO 500000137402 (320545)
- ECO 500000148847 (320433, 320434, 320435)

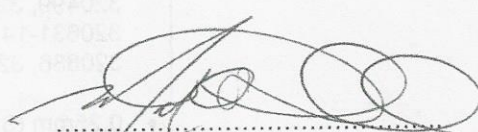
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained under the premises of the manufacturer.

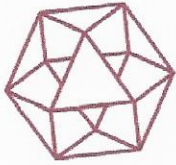
<b>Harmonized standards:</b>	EN 556-1:2001, EN 1041:2008, EN ISO 15223-1:2016, EN ISO 10993 series, EN ISO 11137-1:2015, EN ISO 11137-2:2015 EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 13485:2012&2016, EN ISO 14971:2012, EN 62366:2008
<b>Non-harmonized standards:</b>	ISO 11608-1:2014, ISO 11608-2:2012, ISO 9626:1991/Amd.1:2001(E), ISO 2859-1:1999, ISO 11137-3:2006
<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>	252.128
<b>Date of issuance of original CE Certificate:</b>	22 February 1995

Date: 03 April 2019

Date: 4 April 2019

  
Aurélie CHAUDIER  
Regulatory Affairs Manager  
BD Medical – Diabetes Care EU

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



**NSAI**

# Quality System Approval Certificate

## Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated  
Notified Body, (identification number 0050), for the purposes of the European Communities  
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

**APPROVES THE QUALITY SYSTEM APPLIED BY**

# Becton Dickinson and Company

**1 Becton Drive  
Franklin Lakes  
NJ 07417  
USA**

*to the Product Family*

**Autoinjector Needles (BD™, BD Micro-Fine™, BD Micro-Fine™+, BD  
Micro-Fine™ Plus, BD Micro-Fine Ultra™, BD Micro-Fine Ultra™ PRO,  
BD Ultra-Fine™, BD Ultra-Fine™ PRO, BD Ultra-Fine™ 2nd Gen, BD  
Nano™, BD Viva™, BerliFine® Micro and Accu-Fine® Pen Needles)**

**GMDN Code: 44127**

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices Annex V.  
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of  
Conformance for this product family is hereby authorised.*

<b>Registration Number:</b>	<b>252.128</b>
<b>Original Approval:</b>	<b>22 February 1995</b>
<b>Last Amended on:</b>	<b>05 February 2021</b>
<b>Remains valid until:</b>	<b>26 May 2024</b>

**Signed:**

Approved by:  
Dr. Caroline Dore Geraghty  
Director, Medical Devices

Approved by:  
Dr. Elaine Darcy  
European Medical Device Operations Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**  
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI  
**National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**

