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

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EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson and Company 1 Becton Drive Franklin Lakes, New Jersey 07417, USA
Authorized Representative:	BD Medical – Diabetes Care Becton Dickinson France S.A.S. 11, rue Aristide Bergès, BP 4 38801 Le Pont-de-Claix Cedex, France
Manufacturing Sites:	• Becton Dickinson and Company Pottery Road – Dun Laoghaire – Co. Dublin – Ireland • Becton Dickinson and Company Limited Donore Road – Drogheda – Co Louth – Ireland • BD Medical – Diabetes Care 1329 West Highway 6 – Holdrege – NE 68949 – USA • Becton Dickinson Medical (S) Pte Ltd. 30 Tuas Avenue 2 – Singapore- Singapore 639461 • Becton Dickinson Medical Devices Co., Ltd. Suzhou No 1 Liangpu Street – Suzhou Industrial Park – Jiangsu, P.R. China
Products:	**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** existing in the following presentations: • 0,33mm (29G) x 12,7mm: 320117, 320167, 320180, 320188, 320189, 320207, 320216, 320304, 320473, 320516, 320630, 320633, 320652, 320672, 320690, 320790, 325118, 47250082, 47286482, 47338782, 47362282, 47530082 • 0,30mm (30G) x 8mm: 320164, 320190, 320190-14, 320214, 320305, 320474, 320474-14, 320517, 320519, 320591, 320653, 320691, 320692 • 0,25mm (31G) x 8mm: 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 • 0,25mm (31G) x 6mm: 320523, 320655, 320675, 320687, 320733, 320734, 320736, 320737, 320739, 320743

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Products (continued):	• 0,25mm (31G) x 5mm: 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 • 0,23mm (32G) x 6mm: 320656, 320676, 320683 • 0,23mm (32G) x 4mm: 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 • 0,6mm (23G) x 7mm: 47364902
Classification:	IIa, Annex IX, Rule 6
Conformity Assessment Route:	Annex V and Annex VII
GMDN	• GMDN code: 44127 • GMDN term: Autoinjector needle

* 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.

Harmonized standards:	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
Non-harmonized standards:	ISO 11608-1:2014, ISO 11608-2:2012, ISO 9626:1991/Amd.1:2001(E), ISO 2859-1:1999, ISO 11137-3:2006
Notified Body:	NSAI (National Standards Authority of Ireland) 1 Swift Square, Northwood, Santry, Dublin 9, Ireland Notified Body Number: 0050
CE Certificate number:	252.128
Date of issuance of original CE Certificate:	22 February 1995

Date: 03 April 2019

Aurélie CHAUDIER
Regulatory Affairs Manager
BD Medical – Diabetes Care EU

Date: 4 April 2019

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

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.*

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

Signed:

C Dore Geraghty

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

Elaine Darcy

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.