

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

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

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:	<ul style="list-style-type: none"> • 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:	<p>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:</p> <ul style="list-style-type: none"> • <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 • <u>0.30mm (30G) x 8mm</u>: 320164, 320190, 320190-14, 320214, 320305, 320474, 320474-14, 320517, 320519, 320591, 320653, 320691, 320692 • <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, 324836, 324839, 325108, 325117 • <u>0.25mm (31G) x 6mm</u>: 320523, 320655, 320675, 320687, 320733, 320734, 320736, 320737, 320739, 320743, 324837

TITLE: EC Declaration of Conformity for BD Pen Needles

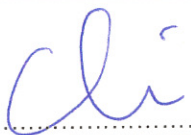
Products (continued):	<ul style="list-style-type: none"> • <u>0,25mm (31G) x 5mm</u>: 320120, 320130, 320165, 320165-15, 320212, , 320424, 320433, 320470, 320498, 320518, 320522, 320535, 320545, 320569, 320590, 320594, 320595, 320632, 320632-14, 320632-15, 320632-17, 320635, 320647, 320650, 320657, 320659, 320666, 320677, 320684, 320693, 320794, 324835, 324840, 325107 • <u>0,23mm (32G) x 6mm</u>: 320656, 320676, 320683 • <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, 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, 324838, 325106, 325115 • <u>0,6mm (23G) x 7mm</u>: 47364902
Classification:	Ila, Annex IX, Rule 6
Conformity Assessment Route:	Annex V and Annex VII
GMDN	<ul style="list-style-type: none"> • GMDN code: 44127 • GMDN term: Autoinjector needle

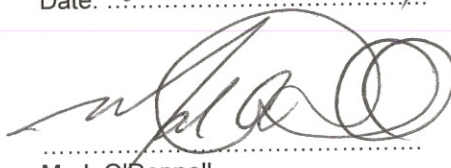
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained under the premises of the manufacturer.

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: 01 July 2019.....

Date: 26 June 2019.....


.....
Aurélie CHAUDIER
Regulatory Affairs Manager
BD Medical – Diabetes Care EU


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