

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



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, NJ 07417, USA
Authorised 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 Site:	BD Medical Diabetes Care 1329 West Highway 6, Holdrege, NE 68949, USA
Products:	<p>BD Micro-Fine™ +, BD Micro-Fine™ Plus, Micro-Fine™, BD Micro-Fine™ IV, Ultra-Fine™ and Ultra-Fine™ II Insulin Syringes and Plastipak™ Syringes existing in the following presentations:</p> <p><u>Plastipak™ Syringes:</u></p> <ul style="list-style-type: none"> ▪ 1ml Plastipak™ Syringe, 26Gx12,7mm: REF 305501, 471329 ▪ 1ml Plastipak™ Syringe, 27G x12,7mm: REF 471492, 324701 ▪ 1ml Plastipak™ Syringe, 27Gx10mm: REF 305502 <p><u>Insulin Syringes:</u></p> <ul style="list-style-type: none"> ▪ 1ml U40, 29Gx12,7mm: REF 320801, 320910 ▪ 1ml U40, 30Gx8mm: REF320911 ▪ 1ml U100, 27G x12,7mm: REF 328415 ▪ 1ml U100, 29Gx12,7mm : REF 320841, 320909, 320924, 324883, 324891, 320931, 324827, 326110, 326719 ▪ 1ml U100, 30Gx8mm: REF 320929, 324899, 320935, 326702 ▪ 1ml U100, 31Gx8mm: REF 328820 ▪ 1 ml U100, 31Gx6mm: REF 324903, 324905, 326674, 324924 ▪ 0,5ml U40, 30Gx 8mm: REF 324876 ▪ 0,5ml U100, 29Gx12,7mm: REF 320921, 320926, 324882, 324892, 324824, 326769, 326105 ▪ 0,5ml U100, 30Gx8mm: REF 320843, 320927, 320930, 324881, 324893, 320933, 324825, 326725 ▪ 0,5ml U100, 31Gx8mm: REF 328821 ▪ 0,5ml U100, 31Gx6mm: REF 324901, 324904, 326675, 324923 ▪ 0,3ml U100, 29Gx12,7mm: REF 326103 ▪ 0,3 ml U100, 30Gx 8mm (½ unit scale): REF 320829, 320839, 320840, 324826 ▪ 0,3 ml U100, 31Gx 8mm: REF 328822 ▪ 0,3 ml U100, 31G x 6mm: REF 324900, 324922
Classification:	Ila
Conformity Assessment Route:	Annex V and Annex VII
GMDN:	<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

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.

Harmonised Standards:	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
Non-Harmonised Standards:	ISO 8537:2016, ISO 7864:2016, ISO 7886-1:1993/COR 1:1995, ISO 9626:2016, ISO 2859-1:1999, EN ISO 11137-3: 2017, ANSI/AAMI/ISO ITR 13004:2013
Notified Body:	NSAI (National Standards Authority of Ireland) 1 Swift Square, Northwood, Santry, Dublin 9, Ireland Notified Body Number : 0050
CE Certificate Number:	252.140
Date of issuance of the original CE certificate:	7 April 1995

Date: 23 March 2021



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

Date: **March 23, 2021**
.....



.....
Avital Merl
Director – Regulatory Affairs BD Medical –
Diabetes Care, US

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

<u>REVISION HISTORY</u>		
Current Version Prepared By: Laura DESLANDES-AZAIEZ		
REV.	Revision Description	Releasing ECO (if applicable)
A	Initial release according to new template	-
B	Addition of Pearl SKUs for ANZ (324900, 324901, 324903, 326674, 326675). Update of standards versions.	500000046118 500000046132 500000046119 500000041227 500000041228
C	Addition of 6mm 0,3ml ½ unit for Italian tender (324910 and 324922).	500000066977
D	Update to N ISO 11137-1:2015 and EN ISO 11137-2:2015	
E	Updated Standards: - Harmonized standards: Withdrawn EN 980:2008 and replaced by EN ISO 15223-1:2016, - Non Harmonized standards: Withdrawn EN ISO 15223-1: 2012 Withdrawal of 324910 SKU	
G	Harmonized standards: -- Updated to ISO 13485 to 2016 version - Updated EN ISO 11137-3 to 2017 version	
H	Withdrawal 320722 / 324811 / 320932 / 320842. Addition of Saudi SKUs 324923 / 324924 Updated Compliance to Standards: - Harmonized standards: Withdrawn EN 980:2008 and replaced by EN ISO 15223-1:2016, - Non Harmonized standards: Withdrawn EN ISO 15223-1: 2012 - Updated ISO 8537:2007 to ISO 8537:2016 - Updated ISO 11137-3:2006 to ISO 11137-3:2017	
I	- Updated ISO 7864:1993 to ISO 7864:2016. - Updated ISO 9626:12991/Amd.1:2001 to ISO 9626:2016	
J	Moves 324922 to 0,3ml, 31Gx6mm	Oct 2020
K	Removed rev# and type of document Removed 324701 and 471488 Added reference to ANSI/AAMI/ISO ITR 13004:2013	March 2021
	Added 324701 ANSI/AAMI/ISO ITR 13004:2013 moved to non-HS	