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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:	BD Micro-Fine™ +, Micro-Fine™ Plus, Micro-Fine™, Micro-Fine™ IV, Ultra-Fine™ and Ultra-Fine™ II Insulin Syringes and Plastipak™ Syringes existing in the following presentations: Plastipak™ Syringes: ▪ 1ml Plastipak™ Syringe, 26Gx12,7mm: REF 305501, 471488, 471329 ▪ 1ml Plastipak™ Syringe, 27G x12,7mm: REF 471492, 324701 ▪ 1ml Plastipak™ Syringe, 27Gx10mm: REF 305502 Insulin Syringes: ▪ 1ml U40, 29Gx12,7mm: REF 320801, 320910 ▪ 1ml U40, 30Gx8mm: REF 320722, 320911 ▪ 1ml U100, 27G x12,7mm: REF 328415 ▪ 1ml U100, 29Gx12,7mm : REF 320841, 320909, 320924, 324811, 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 ▪ 0,5ml U40, 30Gx 8mm: REF 324876 ▪ 0,5ml U100, 29Gx12,7mm: REF 320921, 320842, 320926, 324882, 324892, 320932, 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 ▪ 0,3ml U100, 29Gx12,7mm: REF 326103 ▪ 0,3 ml U100, 30Gx 8mm (½ unit scale): REF 320829, 320839, 320840, 324826, 324910, 324922* ▪ 0,3 ml U100, 31Gx 8mm: REF 328822 ▪ 0,3 ml U100, 31G x 6mm: REF 324900
Classification:	Ila
Conformity Assessment Route:	Annex V and Annex VII
GMDN:	<u>Insulin Syringes</u>: 38501 – Insulin syringe, fixed-needle <u>Plastipak™ Syringes</u>: 35904 – Metered-delivery hypodermic syringe

* The CE mark is affixed to the labeling of this product reference from ECO500000066977 implementation

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 980:2008, 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 13485:2012, EN ISO 14971:2012, EN ISO 22442-1:2007, EN 62366:2008
Non-Harmonised Standards:	ISO 8537:2007, ISO 7864:1993, ISO 7886-1:1993/COR 1:1995, ISO 9626:1991/Amd.1:2001, ISO 2859-1:1999, EN ISO 11137-3:2006, EN ISO 15223-1:2016
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 June 2017



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Date: 05 July 2017



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