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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: <u>Plastipak™ Syringes:</u> ▪ 1ml Plastipak™ Syringe, 26Gx12,7mm: REF 305501, 471488, 471329 ▪ 1ml Plastipak™ Syringe, 27G x12,7mm: REF 471492, 324701 ▪ 1ml Plastipak™ Syringe, 27Gx10mm: REF 305502 <u>Insulin Syringes:</u> ▪ 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, 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

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.

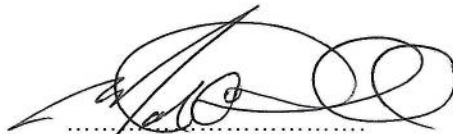
Harmonised Standards:	EN 556-1:2001/AC:2006, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 10993 series, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006 & AC:2009, EN ISO 11737-2:2009, EN ISO 13485:2012, EN ISO 14971:2012, EN ISO 22442-1:2007, EN 62366:2008
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,
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: 12 Nov 2018



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Date: 13 Nov 2018



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