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
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France
Tel: +33 (0)4.76.68.36.36
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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™ +, 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: Plastipak™ Syringes: ▪ 1ml Plastipak™ Syringe, 26Gx12,7mm: REF 305501, 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: 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:	IIa
Conformity Assessment Route:	Annex V and Annex VII
GMDN:	Insulin Syringes: 38501 – Insulin syringe, fixed-needle Plastipak™ Syringes: 35904 – Metered-delivery hypodermic syringe

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

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

Date: March 23, 2021

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

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

REVISION HISTORY

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	

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

Hypodermic Syringes, insulin and general use (BD Micro-Fine™ +, BD Micro-Fine™ Plus, Micro-Fine™ IV, Ultra-Fine™ and Ultra-Fine™ II Insulin Syringes and Plastipak™ Allergy Syringes)

GMDN Code: 38501, 35904

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:	**252.140**
Original Approval:	**07 April 1995**
Last Amended on:	**15 April 2020**
Remains valid until:	**25 May 2024**

Signed:

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

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.

December 2023

Notified Body Confirmation Letter

Reference: **NBCL0069.01**
Becton Dickinson and Company
BD Needles and BD Syringes with Needles
NSAI File Number 745.026

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To whom it may concern

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that National Standards Authority of Ireland (NSAI), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0050 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ
07417, USA
SRN Number : US-MF-000019182

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC

(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Dr Majella Geraghty
European Medical Device Operations Manager
Medical Devices, NSAI

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NSAIinc.com

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
038290BQUKXVUKHW **BD PrecisionGlide™ Needle (Sterile)**	IIa	n/a	252.232 NSAI 0050
038290OGBPJDLC74 **BD Plastipak™ 3mL Syringe (Luer-Lok™ Tip) with BD PrecisionGlide™ Needle**	IIa	n/a	252.231 NSAI 0050
038290RBYLIRPGGS **BD 1mL Syringe (Luer Slip Tip) with BD PrecisionGlide™ Needle**	IIa	n/a	252.231 NSAI 0050
038290CELCHUNBYR **BD Eclipse™ Needle (Sterile)**	IIa	n/a	252.232 NSAI 0050
038290LDDVACHH4E **BD Syringe (Luer-Lok™ Tip) with BD Eclipse™ Needle**	IIa	n/a	252.231 NSAI 0050
038290FVZSMFYFNV **BD Eclipse™ Needle (BNS)**	IIa	n/a	252.231 NSAI 0050
038290AEMSZTUVB9 **BD Eclipse™ Needle (BNS)**	IIa	n/a	252.231 NSAI 0050
038290LGUMWMFDFR **BD Eclipse™ Needle with SmartSlip™ Technology (Sterile)**	IIa	n/a	252.232 NSAI 0050

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
038290ABUAEXEZZE **BD Eclipse™ Needle with SmartSlip™ Technology (BNS)**	IIa	n/a	252.232 NSAI 0050
038290SPLQSMSXPZ **BD SafetyGlide™ Needle (Sterile)**	IIa	n/a	252.232 NSAI 0050
038290VIERILKKFN **BD Syringe with BD SafetyGlide™ Needle**	IIa	n/a	252.232 NSAI 0050
038290ABZASTHM5F **BD SafetyGlide™ Syringe**	IIa	n/a	252.231 NSAI 0050

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
n/a	n/a	n/a	n/a

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023.12.12	NBCL0070.01	Initial issue