

DECLARATION OF CONFORMITY



Legal Manufacturer:	Becton, Dickinson and Company Limited, Donore Road, Drogheda, Co. Louth, Ireland.
Authorised Representative:	NA
Manufacturing Site:	Manufactured on behalf of Becton, Dickinson and Company, Limited by: Becton Dickinson S.A. Crta. Mequinenza s/n. 22520 – Fraga HUESCA – SPAIN
Products:	BD Microlance™ 3 Needles (see attached list for the different types)
Classification:	Class IIa, Rule 6
Conformity Assessment Route:	Annex VII and Annex V
GMDN:	59230

We herewith declare that for the above mentioned products their product design meets the provisions of the European Medical Device Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer or subcontractor.

Harmonized standards:	EN 556-1:2001/AC:2006, EN 1041:2008, EN1707:1996, EN 20594-1:1993/AC:1996, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-3:2014, EN ISO 10993-4:2009, EN ISO 10993-5:2009, EN ISO 10993-7:2008/AC2009, EN ISO 10993-11:2009, EN ISO 10993-12:2012, EN ISO 10993-13:2010, EN ISO 10993-15:2009, EN ISO 10993-17:2009; EN ISO 10993-18:2009; EN ISO 11135-1:2007, EN ISO 11138-2:2009, EN ISO 11737-1:2006/AC:2009, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 13485:2016/AC:2016, EN 14155:2011/ AC:2011, EN ISO 14971:2012, EN ISO15223-1:2016,
Non -Harmonised Standards	ISO 14644-1:1999, EN ISO 10993-2:2006, ISO 10993-10:2009, ISO 9626: 1995, ISO 2859-1:1999, ISO 7864:2016, ISO 594-1:1993, ISO 594-2:1998; ISO 6009; 1995/COR 2008
Notified Body:	NSAI 1 Swift Square, Northwood, Santry Dublin 9, Ireland Telephone: 353-1-807-3800 Number of Notified Body: 0050
CE Certificate number:	252.157
Date of issue of original CE certificate:	24 July 2012

Date: 04 November 2019

Name Andrew Roche
Function QA/RA

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BD Microlance™ 3 Needles

STERILE NEEDLES

CATALOG No.	PRODUCT DESCRIPTION	
	(Imperial, inch)	(S.I.) mm
300094	22G x 2	0.7 x 50
300300	26G x 3/8	0.45 x 10
300400	25G x 1	0.5 x 25
300600	25G x 5/8	0.5 x 16
300635	27G x 1/2	0.4 x 13
300637	16G x 1/2	1.6 x 40
301155	21G x 2	0.8 x 50
301500	19G x 1/2	1.1 x 40
301700	19G x 1	1.1 x 25
301750	19G x 2	1.1 x 50
301900	18G x 2	1.2 x 50
302200	27G x 3/4	0.4 x 19
303800	26G x 1/2	0.45 x 13
304000	30G x 1/2	0.3x 13
302809*	30G x 1/2	0.3x 13
304100	24G x 1	0.55 x 25
304300	26G x 5/8	0.45 x 16
304622	18G x 1/2	1.2 x 40

***Pharmaceutical Quality**

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NON-STERILE NEEDLES (BULK)

CATALOG No.	PRODUCT DESCRIPTION	
	(Imperial, inch)	(S.I.) mm
300206	25G X 5/8	0.5 x 16
300284	21G X 5/8	0.8 x 16
300403	25G X 1	0.5 x 25
300801	23G X 1	0.6 x 25
300802	21G X 1 ½	0.8 x 40
300806	21G X 1	0.8 x 25
300807	20G X 1	0.9 x 25
300808	20G X 1 ½	0.9 x 40
300901	22G X 1 ¼	0.7 x 30
300932	30G X ½	0.3 x 13
301296	27G X ½	0.4 x 13
301530	19G X 1 ½	1.1 x 40
302424	14G X 1 ¼	2.1 x 30
303803	26G X ½	0.45 x 13
304623	26G X 3/8	0.45 x 10
304627	23G X 1	0.6 x 25
304630	21G X 2	0.8 x 50
304636	18G X 2	1.2 x 50
304637	27G X ¾	0.4 x 19
304641	24G X 1	0.55 x 25
304644	18G X 1 ½ SB TW	1.2 x 40
304728	22G X 1	0.7 x 25
304729	22G X 1 ½	0.7 x 40
305146	23G X 1 ¼	0.6 x 30
306030	25G X 5/8	0.5 x 16

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