



DECLARATION OF CONFORMITY

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|-------------------------------------|---|
| 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; sterile 59229; non-sterile |

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 and Irish Regulation; S.I. No. 252 of 1994 (as amended by Regulation 5 of S.I. 110/2009) concerning medical devices. All supporting documentation is retained at the premises of the manufacturer or subcontractor.

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| Harmonized standards: | EN 556-1:2001/AC:2006, EN 980:2008, EN 1041:2008/A1:2013, EN1707:1996, EN 20594-1:1993/AC:2009, 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 13485:2012, ISO13485:2003, EN 14155:2011, EN ISO 14971:2012, |
| Non -Harmonised Standards | ISO 14644-1:1999, ISO 10993-2:2006, ISO 10993-10:2009, ISO 9626: 1995, ISO 2859-1:1999, ISO 7864-1:1996; ISO15223-1:2012, 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: 23 November 2017

Name Andrew Roche
Function QA/RA
Business Unit Becton, Dickinson and Company Limited

Date: 23 November 2017

Cormac Reynolds
Director
Becton, Dickinson and Company Limited

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BD MICROLANCE 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 1/2 | 1.6 x 40 |
| 301155 | 21G x 2 | 0.8 x 50 |
| 301500 | 19G x 1 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 1/2 | 1.2 x 40 |

***Pharmaceutical Quality**

DECLARATION OF CONFORMITY

BD MICROLANCE NEEDLES

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 | 21Gx 1 | 0.8 x 25 |
| 300807 | 20Gx 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 1½ | 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 | 21Gx2 | 0.8 x 50 |
| 304636 | 18G X 2 | 1.1 x 50 |
| 304637 | 27G X ¾ | 0.4 x 19 |
| 304641 | 24G X 1 | 0.55 x 25 |
| 304644 | 18G X 1½ SB TW | 1.2 x 40 |
| 304728 | 22G X 1 | 0.7 x 25 |
| 304729 | 22G X 1½ | 0.7 x 40 |
| 305146 | 23G X 1 ¼ | 0.6 x 30 |
| 306030 | 25G x 5/8 | 0.5 x 16 |