

## DECLARATION OF CONFORMITY



|                              |  |
|------------------------------|--|
| Legal Manufacturer:          | Becton, Dickinson and Company Limited,<br>Donore Road,<br>Drogheda,<br>Co. Louth, Ireland.   |
| Authorised Representative:   | NA   |
| Manufacturing Site:          | Manufactured on behalf of Becton, Dickinson and Company, Limited by:<br><br>Becton Dickinson S.A.<br>Camino Valdeoliva s/n, 28750 San Agustín de Guadalix , Madrid, Spain. |
| Products:                    | BD Plastipak™ Syringes and BD™ Perfusion Syringes (see attached list for the different types)  |
| Classification:              | Class IIa,<br>Rule 6, Plastipak<br>Rule 2, Perfusion   |
| Conformity Assessment Route: | Annex VII and Annex V  |
| GMDN:                        | 47017  |

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.

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|---|---|
| Harmonized standards:                     | EN 556-1:2001/AC:2006, EN ISO15223-1:2016, 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 13485:2016, EN 14155:2011, EN ISO 14971:2012, EN 62366:2008 |
| Non -Harmonised Standards                 | ISO 14644-1:1999, EN ISO 10993-2:2006, ISO 10993-10:2009, ISO 9626: 1995, ISO 2859-1:1999, ISO 7886-1:1998, ISO 7886-2:1998.; ISO 594-1:1993, ISO 594-2:1998;   |
| Notified Body:                            | NSAI<br>1 Swift Square, Northwood, Santry<br>Dublin 9, Ireland<br>Telephone: 353-1-807-3800<br>Number of Notified Body: 0050  |
| CE Certificate number:                    | 252.156   |
| Date of issue of original CE certificate: | 24 July 2012  |

Date: 07 May 2019

Name Andrew Roche  
Function QA/RA

BD Plastipak and Perfusion

Revision Number: 25

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Page 1 of 3

## DECLARATION OF CONFORMITY

### BD Plastipak and Perfusion Syringes

#### STERILE SYRINGES

| CATALOG No. | PRODUCT DESCRIPTION   |
|-------------|---|
| 300136      | BD™ Perfusion 50ml Syringe with DN 14G x 1¼" Needle                           |
| 300137      | BD™ Perfusion 50ml Spl Syringe  |
| 300138      | BD™ Perfusion 50ml Syringe - Amber with DN 14G x 1¼"                          |
| 300139      | BD™ Perfusion 50ml Syringe - Amber  |
| 300605      | BD Plastipak™ 100ml 3 PCS catheter Spl Syringe                                |
| 300613      | BD Plastipak™ 20ml Luer Tip Syringe   |
| 300629      | BD Plastipak™ 20ml Luer Lok™ Syringe  |
| 300865      | BD Plastipak™ 50ml Luer Lok™ Syringe  |
| 300866      | BD Plastipak™ 50ml Luer Tip Syringe   |
| 300867      | BD Plastipak™ 50ml Catheter Tip Syringe                                       |
| 300869      | BD Plastipak™ 50ml Luer Lok™ Syringe- Amber                                   |
| 301183      | BD Plastipak™ 20ml Luer Tip Syringe   |
| 301189      | BD Plastipak™ 20ml Luer Lok™ Syringe  |
| 301190      | BD Plastipak™ 20ml Luer Tip Syringe with 21G x 1½" Thin Wall Needle           |
| 301229      | BD Plastipak™ 30ml Luer Lok™ Syringe  |
| 301231      | BD Plastipak™ 30ml Luer Tip Syringe   |
| 302237      | BD Plastipak™ 20ml Luer-Lok™ Convenience Pack                                 |
| 302238      | BD Plastipak™ 50ml Luer-Lok™ Convenience Pack                                 |
| 302239      | BD™ Perfusion 50 ml Luer-Lok™ Convenience Pack                                |
| 302532      | BD Plastipak™ 20ml Luer Tip Syringe (Brazil, Peru, Argentina)                 |
| 302807      | BD Plastipak™ 20ml Luer Lok™ Syringe/ Pfizer                                  |
| 309742      | BD Plastipak™ 50ml Luer Lok™ Syringe with 14G 1¼" Microlance 3 Needle         |
| 309743      | B BD Plastipak™ 50ml Luer Lok™ Syringe-Amber with 14G 1¼" Microlance 3 Needle |
| 309744      | BD Plastipak™ 50ml Luer Lok™ Syringe with 18G x 1" BF Needle                  |
| 309745      | BD Plastipak™ 50ml Luer Lok™ Syringe with 18G x 1½" BF Needle                 |
| 309746      | BD Plastipak™ 50ml Luer Lok™ Syringe-Amber with 18G x 1" BF Needle            |
| 309747      | BD Plastipak™ 50ml Luer Lok™ Syringe-Amber with 18G x 1½" BF Needle           |

BD Plastipak and Perfusion

Revision Number: 25

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Page 2 of 3

## DECLARATION OF CONFORMITY

### NON-STERILE SYRINGES (BULK)

| CATALOG No. | PRODUCT                                      |
|-------------|--|
| 300220      | BD Plastipak™ 20ml Luer Tip Syringe Bulk     |
| 300223      | BD Plastipak™ 50ml Luer Lok™ Syringe Bulk    |
| 300224      | BD Plastipak™ 50ml Luer Tip Syringe Bulk     |
| 300228      | BD Plastipak™ 50ml Catheter Tip Syringe Bulk |
| 302055      | BD Plastipak™ 20ml Luer Lok™ Syringe Bulk    |

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**BD Plastipak and Perfusion**

**Revision Number: 25**

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Page 3 of 3

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