

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. 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, Rule 6, Plastipak 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.

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 1 Swift Square, Northwood, Santry Dublin 9, Ireland Telephone: 353-1-807-3800 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

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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

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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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