



Document Number: DOC DTF0001

TITLE: Declaration of Conformity for BD Syringes with and without Needles

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1 Becton Drive  
Franklin Lakes, New Jersey 07417  
tel 201 847 6800  
www bd com

## DECLARATION OF CONFORMITY

Manufacturer:	Becton, Dickinson and Company 1 Becton Drive, Franklin Lakes, NJ 07417, USA
Authorized Representative:	Becton Dickinson Distribution Center Laagstraat 57, B-9140 Temse- Belgium
Products:	300912 10 mL Syringe (only) Eurographics 302831 20 mL Syringe S/T (48 count box) 309628 1 mL LL Syringe w/o DN 309653 50 mL Syringe Luer Lok 309654 50 mL Slip Tip Syringe 309620 Catheter Tip Syringe 309623 1ml TB Syringe Slip Tip with BD PrecisionGlide™ Needle 27G x 1/2 (0.4mm x 13mm) 309650 30 mL Luer Lok Syringe (40 count box) 302832 30 mL Luer Lok Syringe (56 count box) 309651 30 mL Luer Slip Syringe (40 count box) 302833 30 mL Luer Slip Syringe (56 count box) 305903 1 mL Syringe w/25G x 5/8 SafetyGlide™ Needle 305906 3 mL Syringe w/22G x 1½ SafetyGlide™ Needle 305930 1 mL SafetyGlide™ insulin syringe with 29 G x 1/2 in 305932 1/2 mL SafetyGlide™ insulin syringe with 29 G x 1/2 in RB 305935 3/10 mL SafetyGlide™ insulin syringe with 29 G x 1/2 in RB 305945 1 mL SafetyGlide™ Tuberculin syringe with 27 G x 1/2 in 305946 1 mL SafetyGlide™ Tuberculin syringe with 26 G x 3/8 in 305950 1 mL Allergist tray with 27 G x 1/2 in SafetyGlide 305951 1 mL Allergist tray with 26 G x 3/8 in SafetyGlide 305780 25 G x 5/8 in Eclipse™ 1 mL Luer-Lok™ syringe 305781 25 G x 5/8 in Eclipse™ 3 mL Luer-Lok™ syringe TW 305782 23 G x 1 in Eclipse™ 3 mL Luer-Lok™ syringe TW 305783 22 G x 1 1/2 in Eclipse™ 3 mL Luer-Lok™ syringe 305784 21 G x 1 1/2 in Eclipse™ 3 mL Luer-Lok™ syringe TW 305785 22 G x 1 1/2 in Eclipse™ 5 mL Luer-Lok™ syringe 305786 22 G x 1 1/2 in Eclipse™ 10 mL Luer-Lok™ syringe 305789 27 G x 1/2 in Eclipse™ 1 mL Luer-Lok™ syringe 305934 1/2 mL SafetyGlide Insulin Syringe with 30 G TW x 5/16 in RB 305909 3 mL Syringe with 21G x 1 ½" TW SafetyGlide Needle 305778 1 mL Syringe with 30G x ½" Eclipse Needle 305779 3 mL Syringe with 21G x 1" Eclipse Needle TW 305784 3 mL Syringe with 21G x 1½" Eclipse Needle 305787 3 mL Syringe with 25G x 1" Eclipse Needle TW 305788 3 mL Syringe with 30G x 1½" Eclipse Needle 305924 3 mL Syringe with 25G x 1" SafetyGlide Needle 305927 1 mL Syringe with 27G x 5/8" SafetyGlide Needle 305775 30G x 1/2 Eclipse with 1 mL LS Syringe 305776 27G x 1/2 Eclipse with 1 mL LS Syringe 305777 25G x 5/8 Eclipse with 1 mL LS Syringe 309586 3 mL Syringe S/T 301027 5 mL Syringe Luer-Lok Tip, non sterile 301028 5 mL Syringe Slip Tip, non sterile 301029 10 mL Syringe Luer-Lok Tip (non-sterile) 300860 ½ mL Syringe 27G x 3/8 Intradermal

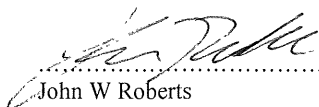
	<p> 301033 30mL Luer Lok Syringe Bulk Non-sterile  301034 830 Slip Tip Syringe Bulk Non-sterile  301035 860 Luer Lok Syringe Bulk Non-sterile  301036 860 Slip Tip Syringe Bulk Non-sterile  301037 2oz Catheter Syringe Bulk Non-sterile  301072 3 mL Luer Lok Syringe w/25G x 1 Needle Bulk Non-sterile  301074 3 mL Luer Lok WWD Syringe w/o shield Bulk Non-sterile  301118 830 Bulk Non-sterile Slip Tip w/o Shield  301119 3 mL Luer Lok WWD Syringe w/22G x 1-1/2 Needle Bulk Non-sterile  301159 3 mL Luer Lok WWD Syringe Bulk Non-sterile (no markings)  301161 3 mL Luer Lok WWD Syringe w/25G x 5/8 Needle Bulk Non-sterile  304134 10 mL Control Syringe Bulk Non-sterile  304406 810 BD Luer-Lok  304416 805 BD™ slip-tip  305500 1 mL Allergist Syringe 28G x ½  305535 ½ mL Allergist Syringe 27G x ½ Regular Bevel  305536 ½ mL Allergist Syringe 27G x 3/8 Intradermal  305537 1 mL Allergist Syringe 26G x ½ Regular Bevel  305538 1 mL Allergist Syringe 26G x ½ Intradermal  305540 1 mL Allergist Syringe 27G x ½ Regular Bevel  305541 1 mL Allergist Syringe 27G x 3/8 Intradermal  305542 1 mL Allergist Syringe 27G x 3/8 Regular Bevel  305620 ½ mL TB Syringe 27G x ½  309648 1 mL Luer Lok Syringe Bulk Non-sterile  305937 3/10 mL SafetyGlide Insulin Syringe with 31 G TW x 5/16 in RB  305539 1 mL Allergist tray with 26G x 3/8 in Needle  309649 5ml LL Syringe EURO 125 S/C  306224 3 ML LL SFTYGLD 25X1  306242 3 ML LL EURO CE  301030 10ML Slip Tip Syringe BNS  301031 20ML LL BNS  301032 20ml S/T BNS  301073 3ML LL BNS  301077 3ML S/T BNS  302830 20ML LL S/C 48  305904 3ML LL W/NDL SFTYGLD 25X5/8 RB TW  305905 3ML LL W/NDL SFTYGLD 23X1 RB TW  309570 3ML LL W/NDL 25X5/8 RB TW  309571 3ML LL W/NDL 23X1 RB TW  309574 3ML LL W/NDL 22X1-1/2 RB  309575 3ML LL W/NDL 21X1 RB TW  309577 3ML LL W/NDL 21X1-1/2 RB TW  309578 3ML LL W/NDL 20X1 RB  309579 3ML LL W/NDL 20X1-1/2 RB  309581 3ML LL W/NDL 25X1 RB TW  309582 3ML LL W/NDL 25X1-1/2 RB TW  309658 3ML LL EURO 200 S/C  30965880 3ML LL EURO 200 S/C  303307 23 G x 1 ½ in Eclipse™ (TW) 5 mL Luer-Lok™ syringe  303306 23 G x 1 ½ in Eclipse™ (TW) 3 mL Luer-Lok™ syringe  303321 10ML LL 21X1-1/2IN SYRINGE ECLIPSE RB TW (combo)  303326 3ML LL W/NDL SYRINGE 23X1-1/2 RB TW SFTYGLD  303327 27X3/8 ID SYRINGE SFTYGLD 1ML W/NDL  303330 1ML W/NDL 27X3/8 ID SYRINGE ALRG SFTYGLD </p>
<b>Classification:</b>	<p> Hypodermic syringes with needles are Class 2A devices, using rule 6 of Annex 9 of the MDD 93/42/EEC. Rule 6 states; “All surgically invasive devices, for transient use, are in Class 2A unless one of the indents applies”. None of the indents apply in this case.  Hypodermic syringes without needles are Class 1 sterile or non-sterile with a measuring function, per Rule 1 of Annex 9 of the MDD 93/42/EEC Rule 1 state: </p>

	“All non-invasive devices are in Class one unless one of the rules set out hereinafter applies” Subsequent rules do not apply.
Conformity Assessment Route:	Annex V and VII
GMDN:	<p><b>GMDN Code:</b> 47017  <b>GMDN Term:</b> General Purpose Syringe, single-use  <b>GMDN Definition:</b> A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used for injection/withdrawal of fluids/gas (e.g., medication) to/from a medical device or the body (i.e., capable of both); a needle is not included. It is intended for various medical applications and is not dedicated to medication administration. At the distal end of the barrel is a male connector (typically Luer-lock/slip type) for the attachment to a hypodermic needle or an administration set. It is typically made of plastic and silicone materials and may have anti-stick plunger allowing smooth plunger movement, either manually or by a syringe pump. This is a single-use device.</p> <p><b>GMDN Code:</b> 35904  <b>GMDN Term:</b> Metered Delivery Hypodermic Syringe  <b>GMDN Definition:</b> A sterile device consisting of a graduated barrel (cylinder) with plunger intended to be used to deliver (inject) or withdraw an accurate metered dose of a fluid to/from the body. The application of the content of this device may be in conjunction with an injector device (transcutaneous delivery) or through the traditional use of a needle (subcutaneous delivery). It may allow for retraction of an attached needle (safety syringe); the needle is not included. This is a single-use device</p> <p><b>GMDN Code:</b> 38501  <b>GMDN Term:</b> Insulin Syringe, fixed- needle  <b>GMDN Definition:</b> A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used to administer an injection of insulin to a patient subcutaneously; a non-retractable needle is included, either attached or detached (usually capped for user protection). The syringe is typically made of plastic and silicone materials and will have plunger anti-sticking properties allowing smooth plunger movement. It can be used by healthcare personnel or patient, and will allow for the aspiration of the pharmaceutical from its container or direct administration to the patient or via an intravenous (IV) port, heparin lock, or saline lock. This is a single-use device.</p>

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 as amended with 2007/47/EC – OJL 247, 21/09/2007. All supporting documentation is retained under the premises of the manufacturer.

Standards of Conformance	<p><i>List of standards and their version</i></p> <p>EN ISO 13485: 2016  EN ISO 14971: 2019  EN 1041: 2008  EN ISO 15223-1: 2016  ISO 7886-1: 1993 COR1 1995*  ISO 7886-1: 2017* (10mL BD Canaan syringes only)  ISO 7886-2: 1996*  EN 556-1: 2001/AC: 2006  EN ISO 20594-1: 1993  EN 1707: 1996  EN 8537: 2007  ISO 7864: 1993  ISO 9626: 1991 AMD1 2001  ISO 6009: 2016  EN ISO 11737-1: 2018  EN ISO 11737-2: 2020  EN ISO 11137-1: 2015  EN ISO 11137-2: 2015</p>
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	EN ISO 11135: 2014/A1: 2019 EN ISO 11138-1: 2017 EN ISO 11138-2: 2017 EN ISO 11607-1: 2020 EN ISO 11607-2: 2020 EN ISO 14155: 2020 EN ISO 22442-1: 2020 IEC 62366-1: 2015+AMD2020 ISO 23908: 2011 EN ISO 10993-1: 2018 EN ISO 10993-2: 2006 EN ISO 10993-3: 2014 EN ISO 10993-4: 2017 EN ISO 10993-5: 2009 EN ISO 10993-6: 2016 EN ISO 10993-7: 2008/AC: 2009 EN ISO 10993-9: 2009 EN ISO 10993-10: 2013 EN ISO 10993-11: 2018 EN ISO 10993-12: 2012 EN ISO 10993-13: 2010 EN ISO 10993-14: 2009 EN ISO 10993-15: 2009 EN ISO 10993-16: 2017 EN ISO 10993-17: 2009 EN ISO 10993-18: 2009 EN ISO 10993-23: 2021 <i>*with exceptions</i>
Notified Body:	NSAI 1 Swift Square, Northwood, Santry, Dublin 9, Ireland Phone : (01) 807 3929; Fax : (01) 807 3996; Medical.Devices@NSAI.ie
EC Certificate number:	252.231
Start of CE marking:	Original Approval: 19 March 1997
Manufacturing Site:	Becton, Dickinson and Company, Route 7 & Grace Way, Canaan, CT 06018, USA BD Medical Surgical Systems, 2153 12 <sup>th</sup> Ave, Columbus, NE 68601, USA. BD Medical-Diabetes Care, 1239 West Highway 6, Holdrege, NE 68949, USA BD Singapore Branch, 30 Tuas Avenue 2, Singapore 639461 Becton Dickinson Infusion Therapy Systems Inc., Trading as Bd Medical Systems, Periferico Luis Donaldo Colosio #579, Nogales, Sonora C.P. 84000 Mexico



John W Roberts  
Sr. Director, Regulatory Affairs  
BD Medical – Medication Delivery Solutions

21 Feb 2023  
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Date