

BD Medical, Medication and Procedural Solutions
 1 Becton Drive
 Franklin Lakes, NJ 07417
 USA
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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:	300910 3 mL Syringe (only) Eurographics 300911 5 mL Syringe (only) Eurographics 300912 10 mL Syringe (only) Eurographics 309661 20 mL Syringe LL (40 count box) 302830 20 mL Syringe LL (48 count box) 301625 20 mL Syringe S/T (40 count box) 302831 20 mL Syringe S/T (48 count box) 300913 20 mL Syringe (only) Eurographics 309628 1 mL LL Syringe w/o DN 309653 60 mL Syringe Luer Lok 309654 60 mL Slip Tip Syringe 309620 Catheter Tip Syringe 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 305904 3 mL Syringe w/25G x 5/8 SafetyGlide™ Needle 305905 3 mL Syringe w/23G x 1 SafetyGlide™ Needle 305906 3 mL Syringe w/22G x 1½ SafetyGlide™ Needle 305907 5 mL Syringe w/22G x 1½ SafetyGlide™ Needle 305908 10 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 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 305782 23 G x 1 in Eclipse™ 3 mL Luer-Lok™ syringe 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 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 305784 3 mL Syringe with 21G x 1½" Eclipse Needle

305787 3 mL Syringe with 25G x 1" Eclipse Needle
 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
 305923 3 mL Syringe with 22G x 1" SafetyGlide Needle
 305928 27G x 5/8 Safetyglide with 1 mL LS Syringe
 305929 25G x 5/8 Safetyglide with 1 mL LS Syringe
 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
 309602 1 mL S/T TB Syringe
 309585 3 mL Syringe LL
 309586 3 mL Syringe S/T
 309573 3 mL Syringe 22G x 1¼"
 309603 5 mL Syringe LL 5
 301603 5 mL Syringe S/T
 301027 5 mL Syringe Luer-Lok Tip, non sterile
 305482 10 mL Syringe Ecc Tip
 305462 10 mL Syringe Ecc Tip (non-sterile)
 301029 10 mL Syringe Luer-Lok Tip (non-sterile)
 301032 20 mL Syringe Slip Tip (non-sterile)
 300853 804 Slip Tip Radiometer Pico
 300860 ½ mL Syringe 27G x 3/8 Intradermal
 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
 301038 804 Slip Tip Syringe w/o Shield Bulk Non-Sterile
 301040 805 Luer Lok Syringe Bulk Non-Sterile w/o Shield
 301041 805 Slip Tip Syringe Bulk Non-sterile w/o Shield
 301042 810 Luer Lok Syringe Bulk Non-sterile w/o Shield
 301043 810 Slip Tip Syringe Bulk Non-sterile w/o Shield
 301044 820 Luer Lok Syringe Bulk Non-sterile w/o Shield
 301048 860 Luer Lok Syringe Bulk Non-sterile w/o Shield
 301072 3 mL Luer Lok Syringe w/25G x 1 Needle Bulk Non-sterile
 301073 3 mL Syringe Luer-Lok Tip w/tip shield Bulk Non-Sterile
 301074 3 mL Luer Lok WWD Syringe w/o shield Bulk Non-sterile
 301077 3 mL Slip Tip WWD Syringe Bulk Non-sterile
 301087 3 mL Slip Tip WWD Syringe w/o shield Bulk Non-sterile
 301107 Non-sterile black 803L/S Arrow with tip shield
 301109 820 L/S Syringe Bulk NS (Arrow Logo)
 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
 301142 3 mL Luer Lok WWD Syringe w/18G 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
 301163 3 mL Luer Lok WWD Syringe Bulk Non-sterile
 301164 3 mL Luer Lok WWD Syringe w/o shield Arrow markings Bulk Non-sterile
 301166 3 mL Luer Lok WWD Syringe Arrow markings Bulk Non-sterile
 304052 804 Non-sterile Syringe w/o shield (Scale markings with BD Logo only)
 304134 10 mL Control Syringe Bulk Non-sterile
 304135 10 mL Control Syringe w/o Tip Shield Bulk Non-Sterile
 304150 804 Slip Tip Syringe 18G x 1½ Bulk Non-sterile
 304179 1 mL Slip Tip Syringe w/TS and Smooth E

	304190 830 Luer Lok Syringe w/o Shield Bulk Non-sterile 304205 820 Luer Lok Syringe Bulk Non-sterile (plain) 304400 805 BD™ slip-tip without shield 304406 810 BD Luer-Lok 304409 20 mL BD Luer-Lok™, bulk, non-sterile, without TS 304416 805 BD™ slip-tip 304418 805 Slip Tip Syringe w/o Shield (Arrow Logo) 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 309623 1 mL S/T TB Syringe 27G x ½ 309624 1 mL S/T TB Syringe 21G x 1 309625 1 mL S/T TB Syringe 26G x 3/8 309626 1 mL S/T TB syringe 25G x 5/8 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 301025 1 mL Syringe Bulk non sterile 305539 1 mL Allergist tray with 26G x 3/8 in Needle 309649 5ml LL Syringe EURO 125 S/C 309658 3ml LL Syringe EURO 200 S/C 309741 1 mL LL Syringe
Classification:	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: "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

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	<i>List of standards and their version</i> EN ISO 13485: 2012 EN ISO 14971: 2012 ISO 15223-1: 2016 EN 980:2008 EN 1041: 2008 EN ISO 11607-1: 2009 EN ISO 11607-2: 2006 EN ISO 10993-1:2009 EN ISO 22442-1: 2007 EN ISO 22442-2: 2007 EN ISO 11135-1: 2007* EN ISO 11137-1: 2015 EN ISO 11137-2: 2015 EN ISO 11138-1: 2006
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	<p>EN ISO 11138-2: 2009 EN ISO 11737-1: 2006 EN 556-1: 2001 EN 20594-1: 1994 Amd 1 1998 (equivalent to ISO 594-1:1986) EN 1707: 1997 (equivalent to ISO 594-2:1998) EN ISO 7886-1: 1998* EN ISO 7886-2: 1998* ISO 8537: 2008* ISO 6009: 1992 Cor 2008* * Some exceptions / exemptions may apply</p>
Notified Body:	<p>NSAI 1 Swift Square, Northwood, Santry, Dublin 9, Ireland</p> <p>Phone : (01) 807 3929; Fax : (01) 807 3996; Medical.Devices@NSAI.ie</p>
EC Certificate number:	252.231
Start of CE marking:	Original Approval: 19 March 1997
Manufacturing Site:	<p>Becton, Dickinson and Company, Route 7 & Grace Way, Canaan, CT 06018, USA BD Medical Surgical Systems, 2153 12th 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</p>



Name: M. Wendy Ballesteros
Function: Director, Regulatory Affairs
BD Medical – Medication Delivery Solutions

2.28.18

Date