

Document Number: DOC DTF0001

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

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### DECLARATION OF CONFORMITY

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| Manufacturer:              | Becton, Dickinson and Company<br>1 Becton Drive, Franklin Lakes, NJ 07417, USA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Authorized Representative: | Becton Dickinson Distribution Center<br>Laagstraat 57, B-9140 Temse- Belgium                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Products:                  | 300912 10 mL Syringe (only) Eurographics<br>302831 20 mL Syringe S/T (48 count box)<br>309628 1 mL LL Syringe w/o DN<br>309653 50 mL Syringe Luer Lok<br>309654 50 mL Slip Tip Syringe<br>309620 Catheter Tip Syringe<br>302832 30 mL Luer Lok Syringe (56 count box)<br>302833 30 mL Luer Slip Syringe (56 count box)<br>305930 1 mL SafetyGlide™ insulin syringe with 29 G x 1/2 in<br>305932 1/2 mL SafetyGlide™ insulin syringe with 29 G x 1/2 in RB<br>305935 3/10 mL SafetyGlide™ insulin syringe with 29 G x 1/2 in RB<br>305945 1 mL SafetyGlide™ Tuberculin syringe with 27 G x 1/2 in<br>305950 1 mL Allergist tray with 27 G x 1/2 in SafetyGlide<br>305934 1/2 mL SafetyGlide Insulin Syringe with 30 G TW x 5/16 in RB<br>301027 5 mL Syringe Luer-Lok Tip, non sterile<br>301029 10 mL Syringe Luer-Lok Tip (non-sterile)<br>301033 30mL Luer Lok Syringe Bulk Non-sterile<br>301035 860 Luer Lok Syringe Bulk Non-sterile<br>305937 3/10 mL SafetyGlide Insulin Syringe with 31 G TW x 5/16 in RB<br>309649 5ml LL Syringe EURO 125 S/C<br>301030 10ML Slip Tip Syringe BNS<br>301031 20ML LL BNS<br>301073 3ML LL BNS<br>301077 3ML S/T BNS<br>302830 20ML LL S/C 48<br>309658 3ML LL EURO 200 S/C<br>303327 27X3/8 ID SYRINGE SFTYGLD 1ML W/NDL<br>309648 1mL Luer Lok Syringe Bulk Non-sterile |
| Intended Purpose:          | <p><b><u>Product Family Intended Use:</u></b><br/>BD Syringes (with and without needles) are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.</p> <p><b><u>BD Allergist Syringe Intended Use:</u></b><br/>These products are used for general purpose injection and aspiration of fluids</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

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|                              | <p>from vials, ampoules and parts of the body below the surface of the skin.</p> <p><b>BD Catheter Tip Syringe Intended Use:</b><br/>These products are intended to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound.</p> <p><b>BD Syringe without Needle Intended Use:</b><br/>These products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.</p> <p><b>BD Syringe with Safety Needle Intended Use:</b><br/>These products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin. The device contains a mechanism which covers the needle point after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.</p>                                                                                                                                                                                                                                                                                                                                                                 |
| Classification:              | <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.</p> <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Conformity Assessment Route: | Annex V and VII                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| GMDN:                        | <p><b>GMDN Code:</b> 47017<br/><b>GMDN Term:</b> General Purpose Syringe, single use.<br/><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<br/><b>GMDN Term:</b> Metered Delivery Hypodermic Syringe<br/><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</p> |

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|  | <p>(subcutaneous delivery). It may allow for retraction of an attached needle (safety syringe); the needle is not included.<br/>This is a single-use device.</p> <p><b>GMDN Code:</b> 38501<br/> <b>GMDN Term:</b> Insulin Syringe, fixed- needle<br/> <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> <p><b>GMDN Code:</b> 63095<br/> <b>GMDN Term:</b> General-purpose syringe/needle<br/> <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 non-retractable needle is included, either attached or detached (usually capped for user protection). It is intended for various medical applications and is not dedicated to medication administration. The syringe 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> |
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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.

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| Standards of Conformance | List of standards and their version<br>EN ISO 13485: 2016<br>EN ISO 14971: 2019<br>EN 1041: 2008<br>EN ISO 15223-1: 2016<br>EN ISO 7886-1: 2018*<br>EN ISO 7886-2: 2020*<br>EN ISO 80369-7: 2021 (Does not apply to SKU 309620)<br>EN 556-1: 2001/AC: 2006<br>EN ISO 20594-1: 1993 Amd1 1998<br>EN 1707: 1996<br>EN 8537: 2016<br>ISO 7864: 2016 |
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|                        | ISO 9626: 2016<br>ISO 6009: 2016<br>EN ISO 11737-1: 2018<br>EN ISO 11737-2: 2020<br>EN ISO 11137-1: 2015<br>EN ISO 11137-2: 2015<br>EN ISO 11138-1: 2017<br>EN ISO 11138-2: 2017<br>EN ISO 11607-1: 2020<br>EN ISO 11607-2: 2020<br>EN ISO 14155: 2020<br>EN ISO 22442-1: 2020<br>IEC 62366-1: 2015+A1: 2020<br>ISO 23908: 2013<br>EN ISO 10993-1: 2020<br>EN ISO 10993-2: 2006<br>EN ISO 10993-3: 2014<br>EN ISO 10993-4: 2017<br>EN ISO 10993-5: 2009<br>EN ISO 10993-6: 2016<br>EN ISO 10993-7: 2008/AC: 2009/AM1: 2022<br>EN ISO 10993-9: 2021<br>EN ISO 10993-10: 2013<br>EN ISO 10993-11: 2018<br>EN ISO 10993-12: 2021<br>EN ISO 10993-13: 2010<br>EN ISO 10993-14: 2009<br>EN ISO 10993-15: 2009<br>EN ISO 10993-16: 2017<br>EN ISO 10993-17: 2009<br>EN ISO 10993-18: 2020<br>EN ISO 10993-23: 2021<br>*with exceptions |
| Notified Body:         | NSAI<br>1 Swift Square,<br>Northwood,<br>Santry, Dublin 9, Ireland<br>Telephone: 353-1-807-3800; <a href="mailto:Medical.Devices@NSAI.ie">Medical.Devices@NSAI.ie</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 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<br>BD Medical Surgical Systems, 2153 12 <sup>th</sup> Ave, Columbus, NE 68601, USA.<br>Embecta/BD Medical-Diabetes Care, 1239 West Highway 6, Holdrege, NE 68949, USA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

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In relation to provision of Annex III of 768/2008/EC set forth by the European Parliament and of the Council on July 9th, 2008. This declaration of conformity is issued under the sole responsibility of the manufacturer for concerning medical devices. All supporting documentation is retained under the premises of the manufacturer.

Signed by:

*John W Roberts*



Signer Name: John W Roberts

Signing Reason: I approve this document

Signing Time: 27-Feb-2025 | 8:21:38 AM PST

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27-Feb-2025

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

Date