

BD Medical, Medical Delivery Solutions

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bd.com

DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton, Dickinson and Company 1 Becton Drive, Franklin Lakes, NJ 07417, USA
Authorised Representative:	Becton Dickinson Distribution Center Laagstraat 57, B-9140 Temse- Belgium
Manufacturing Site(s):	<ul style="list-style-type: none"> • Becton, Dickinson and Company, BD Medical Surgical Systems, 2153 12th Ave, Columbus, NE 68601, USA. • BD Singapore Branch, 30 Tuas Avenue 2, Singapore 639461 • Becton Dickinson S.A., Ctra. Meniquenza, s/n, 22520 Fraga (Huesca) Spain • Becton Dickinson and Company, Route 7 & Grace Way, Canaan, CT 06018 USA • BD (BARD), Boulevard Montebello No 1, Parque Industrial Colonial, Reynosa, Tamaulipas, C.P. 88787
Products:	305900 22 G x 1 ½ in SafetyGlide Needle 305901 25 G x 5/8 in SafetyGlide Needle 305902 23 G x 1 in SafetyGlide Needle 305915 21 G x 1 in SafetyGlide Needle 305916 25 G x 1 in SafetyGlide Needle 305917 21 G x 1 ½ in SafetyGlide Needle 305918 18 G x 1 ½ in SafetyGlide Needle 305921 27G X 5/8 in SafetyGlide Needle 305761 25 G x 1 in Eclipse Needle 305762 23 G x 1 in Eclipse Needle 305763 22 G x 1 ½ in Eclipse Needle 305764 21 G x 1 in Eclipse Needle 305765 21 G x 1 ½ in Eclipse Needle 305766 18 G x 1 ½ in Eclipse Needle 305767 25 G x 1 ½ in Eclipse Needle 305768 22 G x 1 in Eclipse Needle 305769 23 G x 1 ¼ in Eclipse Needle 305760 25 G x 5/8 in Eclipse Needle SmartSlip 305770 27 G x ½ in Eclipse Needle SmartSlip 305771 30 G x ½ in Eclipse Needle SmartSlip 305892 23 G x 1 in Eclipse Needle SmartSlip 305895 21 G x 1 ½ in Eclipse Needle SmartSlip 305886 23 G x 1 ¼ in Eclipse Needle SmartSlip 305887 22G X 1 ¼ in Eclipse Needle SmartSlip 305891 25 G x 1 in Eclipse Needle SmartSlip 305889 27G X ¾ in Eclipse Needle SmartSlip 302436 27 G x 1 ½ in Eclipse Needle SmartSlip 302437 18 G x 1 ½ in Eclipse Needle SmartSlip 305894 21 G x 1 in Eclipse Needle SmartSlip 305899 20 G x 1 in Eclipse Needle SmartSlip

	305888 20G X 1 1/2 in Eclipse Needle SmartSlip
	305757 30 G X 1/2 in Eclipse Needle
	305758 27 G X 1/2 in Eclipse Needle
	305759 25 G X 5/8 in Eclipse Needle
	303671 18 G x 1 1/2 in RB TW Eclipse Needle SmartSlip BNS
	303672 20 G x 1 in RB TW Eclipse Needle SmartSlip BNS
	303673 20 G x 1 1/2 in RB TW Eclipse Needle SmartSlip BNS
	303674 21 G x 1 1/2 in RB TW Eclipse Needle SmartSlip BNS
	303675 22 G x 1 1/4 in RB TW Eclipse Needle SmartSlip BNS
	303676 23 G x 1 in RB TW Eclipse Needle SmartSlip BNS
	303677 23 G x 1 1/4 in RB TW Eclipse Needle SmartSlip BNS
	303678 25 G x 1 in RB TW Eclipse Needle SmartSlip BNS
	305109 27G x 1/2" Needle
	305110 26G x 3/8" Needle
	305127 25G x 1 1/2" Needle
	305136 27G x 1 1/4" Needle
	305143 23G x 3/4" Needle
	305159 22G x 1 1/2" Needle
	305176 20G x 1 1/2" Needle
	305179 20G x 1 1/2" Needle, short bevel
	305186 19G x 1" Needle
	305196 18G x 1 1/2" Needle
	305198 16G x 1 1/2" Needle
	305106 30G x 1/2" Needle
	305122 25G x 5/8" Needle
	305124 25G x 7/8" Needle
	305125 25G x 1" Needle
	305145 23G x 1" Needle
	305120 23G x 1 1/4" Needle
	305142 22G x 3/4" Needle
	305155 22G x 1" Needle
	305156 22G x 1 1/2" Needle
	305165 21G x 1" Needle
	305166 21G x 1 1/4" Needle
	305167 21G x 1 1/2" Needle
	305129 21G x 2" Needle
	305175 20G x 1" Needle
	305187 19G x 1 1/2" Needle
	305195 18G x 1" Needle
	305178 20G x 1" Needle
	305188 19G x 1" Needle
	305189 19G x 1 1/2" Needle
	305115 26G SUB-Q x 5/8" Needle
	305193 23G IM x 1" Needle
	305194 23G IM x 1 1/2" Needle
	305185 18G Fill x 1 1/2" Needle
	305190 21G IV x 1 1/2" Needle
	300745 30 G x 1/2 in Needle, BNS
	301230 27 G x 1/2 in Needle, BNS
	303004 18 G x 1 in Needle, BNS
	303005 18 G x 1 1/2 in Needle, BNS
	303006 19 G x 1 1/2 in Needle, BNS
	303007 20 G x 1 1/2 in Needle, BNS
	303008 21 G x 1 1/2 in Needle, BNS

	<p>303009 22 G x 1 ½ in Needle, BNS 303010 25 G x 5/8 in Needle, BNS 303011 23 G x 1 in Needle, BNS 303012 25 G x 1 in Needle, BNS 303013 18 G x 1 ½ in Needle, BNS 303015 22 G x 1 ½ in Needle, BNS 303018 25 G x 1 ½ in Needle, BNS 305790 18 G x 1 ½ in Eclipse Needle, BNS 305795 25 G x 1 in Eclipse Needle, BNS 305107 30G X ½ in Needle 305108 30G X 1 in Needle 305798 25 G x 5/8 in Eclipse Needle BNS 305814 30 G X ½ in Eclipse Needle BNS 305791 21 G x 1 in TW Eclipse Needle BNS 305792 21 G x 1 ½ in TW Eclipse Needle BNS 305793 22 G x 1 ½ in Eclipse Needle BNS 305794 23 G x 1 in TW Eclipse Needle BNS 305797 22 G x 1 in Eclipse Needle BNS</p>
<p>Classification:</p>	<p>Class IIa, Sterile, Hypodermic 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>Conformity Assessment Route:</p>	<p>Annex V and VII</p>
<p>GMDN Information:</p>	<p>GMDN Code: 59230 GMDN Term: Hypodermic needle, Single Use GMDN Definition: A non-dedicated, sharp bevel-edged, hollow tubular device intended to be inserted beneath the skin of a patient while connected to a noninvasive device (e.g., syringe, secondary medication set) to administer and/or withdraw (aspirate) fluids/drugs; it may also be used for fluid/drug preparation. Some types are designed with a shielding mechanism (e.g., safety cap) for protection from sharp injuries. It is not specifically designed for blood collection or artery puncture, and does not have wings for fixation/placement (i.e., not a blood collection, intra-arterial, or venous butterfly needle). 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.

Harmonized Standards:	EN 556-1: 2001/AC:2006 EN ISO 15223-1:2016 EN 1041: 2008 IEC 62366-1:2015+AMD2020 EN ISO 13485: 2016 EN ISO 14971: 2019 EN ISO 11607-1: 2020 EN ISO 11607-2: 2020 EN ISO 22442-1: 2020 EN ISO 11737-1: 2018 EN ISO 11737-2: 2020 EN ISO 11135 2014/A1: 2019 EN ISO 11137-1: 2015 EN ISO 11137-2: 2015 EN ISO 11138-1:2017 EN ISO 11138-2:2017 EN ISO 14155: 2020 EN ISO 10993-1:2009/AC:2010 EN ISO 10993-3:2014 EN ISO 10993-4:2009 EN ISO 10993-5: 2009 EN ISO 10993-6:2009 EN ISO 10993-7: 2008/AC: 2009 EN ISO 10993-9:2009 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 10993-16:2010 EN ISO 10993-17:2009 EN ISO 10993-18:2009
Non-Harmonized Standards:	EN ISO 20594-1: 1993 EN 1707: 1996 ISO 7864: 1993 ISO 9626: 1991 AMD1 2001 ISO 6009: 2016 ISO 23908: 2011 EN ISO 10993-1: 2018 EN ISO 10993-2: 2006 EN ISO 10993-4: 2017 EN ISO 10993-6: 2016 EN ISO 10993-10: 2013 EN ISO 10993-16: 2017 EN ISO 10993-23: 2021

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

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CE Certificate Number:	252.232
Date of issuance of original CE certificate:	19 March 1997



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14-Apr-2022

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Date: