

BD Medical, Medication and Procedural Solutions

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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:	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 ½ in Eclipse Needle SmartSlip 305757 30 G X ½ in Eclipse Needle 305758 27 G X ½ in Eclipse Needle 305759 25 G X 5/8 in Eclipse Needle 303671 18 G x 1 ½ in RB TW Eclipse Needle SmartSlip BNS 303672 20 G x 1 in RB TW Eclipse Needle SmartSlip BNS 303673 20 G x 1 ½ in RB TW Eclipse Needle SmartSlip BNS 303674 21 G x 1 ½ in RB TW Eclipse Needle SmartSlip BNS 303675 22 G x 1 ¼ in RB TW Eclipse Needle SmartSlip BNS 303676 23 G x 1 in RB TW Eclipse Needle SmartSlip BNS 303677 23 G x 1 ¼ 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
 303009 22 G x 1 1/2 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 1/2 in Needle, BNS
 303015 22 G x 1 1/2 in Needle, BNS
 303018 25 G x 1 1/2 in Needle, BNS
 305790 18 G x 1 1/2 in Eclipse Needle, BNS
 305793 22 G x 1 1/2 in Eclipse Needle, BNS
 305795 25 G x 1 in Eclipse Needle, BNS
 305107 30G X 1/2 in Needle
 305108 30G X 1 in Needle
 305798 25 G x 5/8 in Eclipse Needle BNS
 305814 30 G X 1/2 in Eclipse Needle BNS
 305791 21 G x 1 in TW Eclipse Needle BNS
 305792 21 G x 1 1/2 in TW Eclipse Needle BNS
 305793 22 G x 1 1/2 in Eclipse Needle BNS

	305794 23 G x 1 in TW Eclipse Needle BNS 305797 22 G x 1 in Eclipse Needle BNS
Classification:	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.
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> I.S. EN ISO 13485:2016 EN ISO 14971:2012 EN556-1:2001 COR1 2006 EN ISO 11607-1:2009 EN ISO 11135-1:2007 EN ISO11137-1:2006 EN ISO 10993 Series	ISO 15223-1:2016 EN 980: 2008 I.S. EN 1041:2008 I.S. EN ISO 6009:1992/COR 1 2008 I.S. EN ISO 7864:1993 EN ISO 14155:2011 EN ISO 22442-1&2:2007 EN 20594-1:1994 Amd 1 1998 EN 1707:1997 ISO 23908:2011* *Applies to BD Eclipse Needles (with or without Smartslip) Only
Notified Body:	NSAI 1 Swift Square, Northwood, Santry, Dublin 9 Ireland Notified Body Number 0050 Phone : (01) 807 3929; Fax : (01) 807 3996 ; Medical.Devices@NSAI.ie	
EC Certificate number:	252.232	
Start of CE marking:	Original Approval: 19 March 1997	
Manufacturing Site:	- 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	



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