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BD
Helping all people live healthy lives

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:	Filter and Fill Needles Catalog Numbers: 300779 18G x 1 ½ Nokor 300780 16 G x 1 Nokor 305211 Blunt Fill Needle – Filter, 18G x 1 ½ 305180 Blunt Fill Needle 18G x 1/1/2 305181 Blunt Fill Needle, 18G x 1 305183 Blunt Fill Needle, 20G x 1 *This product is available to be overlabeled with CE compliant labeling *305201 Filter needle 18G x 1½ thin wall NOKOR point
Classification:	Class I, Sterile Filter and Fill Needles are classified as Class 1, Sterile according to Rule 1 of Annex IX which states 'all non-invasive devices are in Class 1 unless one of the rules set out herein apply..' (none of the rules 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:	ISO 594-1:1986 (Identical to I.S.EN 20594-1:1994 Am 1 1998) ISO 594-2:1998 (Identical to I.S. EN 1707:2007) ISO 9626:1991 Am1 2001 EN 556-1:2001 ISO 15223-1:2012 EN 1041:2008 EN ISO 10993-1:2009 EN ISO 11135-1:2007 EN ISO 11137-1:2006 EN ISO 11607-1:2009 EN ISO 13485:2012 EN ISO 14971:2012 EN ISO 22442-1:2007 EN ISO 22442-2:2007
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:	252.308
Start of CE marking:	Original Approval: 02 April 1998
Manufacturing Site:	BD Medical Surgical, 2153 12th Ave, Columbus, NE 68601 USA

Date: September 24, 2013

MW Ballesteros .....

Name: Wendy Ballesteros
Function: Manager, Regulatory Affairs
BD Medical Surgical Systems