

Document Number: DOC DTF0006-01

TITLE: Declaration of Conformity for Fill and Filter Needles

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DECLARATION OF CONFORMITY

Legal 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:	Fill and Filter 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 400066 BD® Blunt Filter NRFit™ Needle, 18G x 1 ½ 400067 BD® Blunt Fill NRFit™ Needle, 18G x 1 ½
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
GMDN:	GMDN Code: 16266 GMDN Term: Medication transfer needle, filtering GMDN Definition: A sterile, slender, sharply-pointed metal tube typically intended to be used in the pharmacy to transfer medication from a vial to another container. It includes an integral filter (e.g., a microporous stainless steel filter) intended to retain micro-particles from the drug as it flows through the needle to reduce the risk of particle contamination of the patient-administered medication. This is a single-use device. GMDN Code: 64357 GMDN Term: Medication transfer straw Definition: A slender flexible tube with a blunt distal end intended to be attached to a syringe to aspirate pharmaceutical fluids from an open vial or ampule during the preparation of medications performed by healthcare professionals (e.g., pharmacists, physicians, nurses); it is not intended to puncture the seal of a vial/container. It is typically made of plastic and may include an integral filter intended to retain micro-particles to reduce the risk of particle contamination of the patient medication. It is not intended for skin injections or tissue manipulation and is not intended for enteral use. This is a single-use device. GMDN Code: 16627 GMDN Term: Medication transfer needle, non-filtering/non-vented Definition: A slender, rigid, sharp or blunt metal tube intended to be attached to a syringe and typically used in the pharmacy to aspirate and transfer fluid medication from a vial/ampule to another container for medication preparation or other purposes. It consists of a short needle sufficient to penetrate the vial stopper and extract all the medication. It is typically of 20 gauge to provide a high-flow rate with minimum coring. It does not include a filter or a back-pressure

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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, and complies with the essential requirements of Council Directive 93/42/EEC as amended above. All supporting documentation is retained under the premises of the manufacturer.	
Standards:	EN ISO 13485:2016 EN ISO 14971:2019 EN 1041:2008 EN ISO 15223-1:2016 EN ISO 20594-1:1993** EN 1707:1996** ISO 7864:1993* ISO 9626:1991 AMD1 2001* EN ISO 11137-1:2015 EN ISO 11137-2:2015 EN ISO 11135:2014/A1:2019 EN ISO 11607-1:2020 EN ISO 11607-2:2020 EN ISO 14155:2020 EN ISO 22442-1:2020 ISO 80369-6:2016*** ISO 80369-20:2015*** IEC 62366-1:2015+AMD2020 EN ISO 11138-1:2017 EN ISO 11138-2:2017 EN ISO 11737-1:2018 EN ISO 11737-2:2020 EN ISO 10993-1:2018 EN ISO 10993-2:2006 EN ISO 10993-3:2014 EN ISO 10993-4:2017 EN ISO 10993-5:2009 EN ISO 10993-6:2016 EN ISO 10993-10:2013 EN ISO 10993-11:2018 EN ISO 10993-12:2021 EN ISO 10993-13:2010 EN ISO 10993-18:2009
Notified Body:	National Standards Authority of Ireland (NSAI) 1 Swift Square Northwood, Santry, Dublin 9, Ireland Phone: (01) 807 3929 Fax: (01) 807 3996 Medical.Devices@NSAI.ie Notified Body Number : 0050
EC Certificate number:	252.308
Start of CE marking:	Original Approval: 02 April 1998
Manufacturing Site:	BD Medical Surgical, 2153 12 th Ave, Columbus, NE 68601 USA Becton Dickinson de México, S.A., de C.V. Cuautitlan, Autopista México - Querétaro Km. 37.5. Parque Industrial Cuamatla, Cuautitlán Izcalli, Estado de México, 54730, Mexico (NRFit Needles Only)

*Some exceptions apply.

** Applies to Luer needles only.

*** Applies to NRFit needles only.



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A handwritten signature in black ink, appearing to read 'Murtaza Rana', is written over a horizontal dotted line.

Murtaza Rana
Sr. Manager, Regulatory Affairs
BD Medical Delivery Solutions

30-November-2021

Date