EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417, USA
Authorised Representative:	Becton Dickinson Distribution Center NV Laagstraat 57 B-9140 Temse Belgium
Manufacturing Site(s):	1mL, 3mL, 5mL and 10mL syringes: Becton, Dickinson and Company Route 7 & Grace Way Canaan, CT 06018, USA 20mL and 50mL syringes: Becton, Dickinson and Company 2153 12th Ave. Columbus, NE 68601, USA
Products:	Bulk, Non-Sterile: 400164 BD® 1mL Syringe NRFit™ Lok 400165 BD® 1mL Syringe NRFit™ Slip 400048 BD® 3mL Syringe NRFit™ Lok 400166 BD® 3mL Syringe NRFit™ Slip 400167 BD® 5mL Syringe NRFit™ Lok 400049 BD® 5mL Syringe NRFit™ Slip 400168 BD® 10mL Syringe NRFit™ Lok 400169 BD® 10mL Syringe NRFit™ Slip 400178 BD® 20mL Syringe NRFit™ Lok 400179 BD® 50mL Syringe NRFit™ Lok Single, Sterile Unit: 400170 BD® 1mL Syringe NRFit™ Lok 400171 BD® 1mL Syringe NRFit™ Slip 400050 BD® 3mL Syringe NRFit™ Lok 400172 BD® 3mL Syringe NRFit™ Slip 400173 BD® 5mL Syringe NRFit™ Lok 400051 BD® 5mL Syringe NRFit™ Slip 400174 BD® 10mL Syringe NRFit™ Lok 400175 BD® 10mL Syringe NRFit™ Slip 400182 BD® 20mL Syringe NRFit™ Lok 400183 BD® 50mL Syringe NRFit™ Lok
Classification:	Class I, Annex IX, Rule 1

Conformity Assessment Route:	Annex V and Annex VII
GMDN:	GMDN Code: 63603 GMDN Term: Neuraxial syringe GMDN Definition: A sterile device consisting of a calibrated barrel (cylinder) with plunger intended for neuraxial applications (to administer medications to neuraxial sites, wound infiltration anaesthesia delivery, and other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes). At the distal end of the barrel is a male connector, designed according to ISO 80369-6 (often referred to as an NRFit connection), intended specifically for connection to neuraxial devices (e.g., needles, catheters, tubing) with the appropriate NRFit connection. This is a single-use device.

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. All supporting documentation is retained at 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 11137-1: 2015 EN ISO 11137-2: 2015 EN ISO 11138-1:2017 EN ISO 14155: 2020*
Non-Harmonized Standards:	ISO 80369-6: 2016 ISO 80369-20: 2015 ISO 7886-1: 1993 COR 11995[1]

[1] With exceptions to section: 12.1

	ISO 7886-2 :1996[2] ISO 10993-1:2018 ISO 10993-4:2017 ISO 10993-5: 2009 ISO 10993-10:2010 ISO 10993-11:2017 ISO 10993-18:2005 ANSI/AAMI/ISO 11137-1: 2006/(R) 2015 & A1:2013 ANSI/AAMI/ISO 11137-2 :2013 ASTM F2096: 2011[3] ASTM F88/F88M: 2015 ASTM F1608: 2009
Notified Body:	National Standards Authority of Ireland (NSAI) 1 Swift Square, Northwood, Santry, Dublin 9, Ireland Notified Body Number: 0050
CE Certificate Number:	252.231
Date of issuance of original CE certificate:	19 March 1997

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

30-November-2021
Date

[2]With exceptions to sections: 13.1, 14.0, 16.3D

[3] With exception to section 4