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:	Syringe with Retracting PrecisionGlide Needle (BD Integra) Catalog Numbers: 305269 BD Integra™ 3ml Syringe with 25G x 5/8" Needle 305270 BD Integra™ 3ml Syringe with 25G x 1" Needle 305271 BD Integra™ 3ml Syringe with 23G x 1" Needle 305272 BD Integra™ 3ml Syringe with 22G x 1½" Needle 305273 BD Integra™ 3ml Syringe with 21G x 1" Needle 305274 BD Integra™ 3ml Syringe with 21G x 1½" Needle 305275 BD Integra™ 18G x 1½" Blunt Fill Needle 305283 BD Integra™ 3ml Syringe 305310 BD Integra™ 25G x 5/8" Needle 305311 BD Integra™ 25G x 1" Needle 305312 BD Integra™ 23G x 1" Needle 305313 BD Integra™ 22G x 1½" Needle 305833 BD Integra™ 18G x 1½" Blunt Filter Needle
Classification:	**Class IIa (BD Integra™ Syringe with Needle, Integra Needles)** BD Integra™ Syringe with needle is a Class IIA Medical Device as per Annex IX, Section III, Rule 6 of the Medical Device Directive 93/42/EEC. Rule 6 reads, "All surgically invasive devices intended for transient use are in Class IIa...". BD Integra™ Syringes are intended for transient use, i.e., continuous use for less than 60 minutes as per Annex IX, Section I, paragraph 1.1 and are surgically invasive as per Annex IX, Section I, paragraph 1.2. Paragraph 1.2 indicates that for the purposes of the directive, devices other than those which produce penetration through a non-established body orifice shall be treated as surgically invasive devices. **Class I Sterile with a measuring function (BD Integra™ Syringe only)** BD Integra™ Syringe without needle is a Class I Medical Device, sterile with a measuring function, as per Annex IX, Section III, Rule 1 of the Medical Device Directive 93/42/EEC. Rule 1 reads, "All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies." Subsequent rules do not apply. **Class I Sterile (BD Integra™ Blunt Fill Needles and Blunt Filter Needles)** BD Integra™ Blunt Fill Needles and Blunt Filter Needles are Class Is Medical Device, sterile, as per Annex IX, Section III, Rule 1 of the Medical Device Directive 93/42/EEC. Rule 1 reads, "All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies." Subsequent rules do not 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, 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 of Conformance:	*List of standards and their version* EN ISO 13485:2016 EN ISO 14971:2019 EN 1041:2008 EN ISO 15223-1:2016 ISO 7864:1993* ISO 7886-1:1993 COR 1 1995* ISO 9626:1991 AMD1 2001* ISO 6009:2016* EN ISO 11137-1:2015 EN ISO 11137-2:2015 EN ISO 11737-1:2018 EN ISO 11737-2:2020 EN 556-1:2001 EN ISO 11138-1:2017 EN ISO 11138-2:2017 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 EN ISO 10993 series IEC 62366-1:2015+AMD2020 *with exceptions
Notified Body:	NSAI 1 Swift Square, Northwood, Santry, Dublin 9, Ireland Phone : (01) 807 3929 Fax : (01) 807 2996 Medical.Devices@NSAI.ie
EC Certificate number:	252.568
Start of CE marking:	Original Approval: 24 February 2003
Manufacturing Site:	• Becton, Dickinson and Company, Route 7 & Grace Way, Canaan, CT 06018, USA • BD Medical Surgical, 2153 12th Avenue, Columbus, NE 68601, USA • Becton Dickinson Infusion Therapy Systems Inc., Periferico Luis Donaldo Colosio #579, Nogales, Sonora C.P. 84048 Mexico

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

30-November-2021
Date