1 Becton Drive
Franklin Lakes, New Jersey 07417
tel: 201.847.6800
www.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
	BD Oral/Enteral Syringe and Tip Cap Catalog Numbers: 305851 1mL BD Oral/Enteral Syringe 305853 3mL BD Oral/Enteral Syringe 305855 5mL BD Oral/Enteral Syringe 305857 10mL BD Oral/Enteral Syringe 302837 20mL BD Oral/Enteral Syringe 302836 30mL BD Oral/Enteral Syringe 305863 60mL BD Oral/Enteral Syringe 302435 BD Oral/Enteral Syringe Tip Cap
Classification:	Class IIa. The BD Oral/Enteral Syringe is classified as a Class IIa Medical Device as per Annex IX, Section III, Rule 5, which reads “All invasive devices with respect to body orfices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa". Class I, Sterile. The BD Oral/Enteral Syringe Tip Cap is classified as 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, which reads “All non-invasive devices are in Class I, unless one of the rules set out herein after 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. 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 7886-1: 1993 COR1 1995* ISO 7886-1: 2017* (10mL BD Canaan syringes only) ISO 7886-2: 1996* EN 556-1: 2001/AC: 2006 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 ISO 11607-1: 2020 ISO 11607-2: 2020 EN ISO 14155: 2020

	EN ISO 22442-1: 2020 IEC 62366-1: 2015+AMD2020 EN ISO 10993-1: 2018 EN ISO 10993-2: 2006 EN ISO 10993-4: 2017 EN ISO 10993-5: 2009 EN ISO 10993-10: 2013 EN ISO 10993-11: 2018 EN ISO 10993-12: 2012 EN ISO 10993-13: 2010 EN ISO 10993-17: 2009 EN ISO 10993-18: 2009 EN ISO 10993-23: 2021 **with exceptions*
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:	252.852
Start of CE marking:	Original Approval: 26 October 2011
Manufacturing Site:	Becton, Dickinson and Company Route 7 and Grace Way Canaan, CT 06018, USA BD Medical Systems 2153 12th Avenue Columbus, NE 68601 USA

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

30-November-2021
Date

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EC DECLARATION OF CONFORMITY

Document Number: VR4310008

Manufacturer:	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom
Authorized Representative:	BD-Switzerland Sàrl Terre Bonne Park-A4 Route de Crassier 17 1262 Eysins Switzerland
Manufacturing Site(s):	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom *Becton, Dickinson and Company 150 South First Avenue, Broken Bow, NE, 68822, USA
Products:	See table below
IVDD Classification:	Non Annex II *In Vitro* Diagnostic Medical Device
IVDD Conformity Assessment Route:	Annex III (excluding Annex III.6)

Catalogue number	Device name	GMDN Code
365305	BD Vacutainer® NaF 6.0mg Na2EDTA 12.0mg Plus Blood Collection Tubes	44208
368520	BD Vacutainer® NaF 3.0mg Na2EDTA 6.0mg Plus Blood Collection Tubes	44208
368521	BD Vacutainer® NaF 6.0mg Na2EDTA 12.0mg Plus Blood Collection Tubes	44208
367933	BD Vacutainer® NaF 3.0mg Na2E 6.0mg Plus Blood Collection Tubes	44208
368201	BD Vacutainer® FX 12.5mg/10mg Plus Blood Collection Tubes	47591
360068	BD Vacutainer® NaF 3.0mg Na2EDTA 6.0mg Plus Blood Collection Tubes	44208

Applies to catalogue #367933

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *in vitro* diagnostic medical devices. This declaration is based on conformity to Annex III (excluding Annex III.6). All supporting documentation is retained under the premises of the manufacturer.

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List of Harmonized Standards:
EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes **EN ISO 14971:2012** Medical Devices – Application of risk management to medical devices **EN 556-1:2001** Sterilisation of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices **EN ISO 11137-1:2015** Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices **EN ISO 11137-2:2015** Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose. **EN ISO 11737-2:2009** Sterilization of medical devices - Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process **EN 14820:2004** Single-use containers for human venous blood specimen collection **EN 62366:2008** Medical devices - Application of usability engineering to medical devices **EN ISO 18113-1: 2011** In vitro diagnostic medical devices – Information supplied by the manufacturer (Labelling). Part 1: Terms, definitions and general requirements (ISO 18113-1:2009) **EN ISO 18113-2: 2011** In vitro diagnostic medical devices – Information supplied by the manufacturer (Labelling). Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009) **EN ISO 15223-1:2016** Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
List of Non-Harmonised Standards:
ISO 14001:2015 Environmental management systems - Requirements with guidance for use **EN ISO 11137-3:2017** Sterilisation of health care product – Radiation – part 3: guidance on dosimetric aspects of development, validation and routine control **EN ISO 11737-1:2018** Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products **ISO 6710:1995** Single-Use Containers for Venous Blood Specimen Collection **EN ISO 14698-1:2003** Cleanrooms and associated controlled environments -- Biocontamination control — Part 1: General principles and methods **EN ISO 14698-2:2003** Cleanrooms and associated controlled environments -- Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data **EN ISO 14644-1:2015** Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness **EN ISO 14644-2:2015** Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration **ISO 2859-1:1999** Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection **ASTM D5276:1998 (R 2009)** Standard Test Method for Drop Test of Loaded Containers by Free Fall **ASTM D999: 2008 (R2015)** Standard Test Methods for Vibration Testing of Shipping Containers **ASTM D4169: 2014** Standard Practice for Performance Testing of Shipping Containers and Systems **ASTM D4728: 2006 (R2012)** Standard Test Method for Random Vibration Testing of Shipping Containers **ASTM D-775: 1980 (R 1986)** Standard Test Method for Drop Test for Loaded Boxes

SIGNED FOR AND ON BEHALF OF: Becton, Dickinson and Company

DATE OF ISSUE: 01-May-2020

Signature: Kay A Taylor

Kay Taylor

Vice President, Regulatory Affairs

BD Life Sciences and IDS

Document Number: VR4310008

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VERSION HISTORY

Current Version Prepared By: A. Gregg

REV.	Version Description
A	Transferred from QDMS to ECC – Version number remained
B	Transfer into new IVD Declaration of Conformity Template (MED-RA-001D)
C	Update EN ISO 11737-1:2006 to EN ISO 11737-1:2018 as per CAPA 325553.
D	Added Authorized Rep: BD Switzerland; updated EN ISO 13486-2012 to 2016; updated authorized signature to Kay Taylor.
E	Added new catalog number, 360068 for prebarcoded product requested by European marketing, ACR PAS-2019-0075 Serialization of Product on Unit Level with Barcode (Universal Specimen Identification – USI).