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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

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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).