Belliver Industrial Estate
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BD
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EC DECLARATION OF CONFORMITY

Manufacturer:	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom
Manufacturing Site(s):	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom

Products:

Catalogue number	Device name	GMDN Code
365300	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
368834	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
365329	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
365330	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
365331	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
365312	BD Vacutainer® K2E 18.0mg Plus Blood Collection Tubes	43865
365314	BD Vacutainer® K2E 7.2mg Plus Blood Collection Tubes	43865
365900	BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	43865
367525	BD Vacutainer® K2E (EDTA) 18.0mg Plus Blood Collection Tubes	43865
367838	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
367386	BD Vacutainer® K2E 18.0mg Plus Blood Collection Tubes	43865
367839	BD Vacutainer® K2E 7.2mg Plus Blood Collection Tubes	43865
367864	BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	43865
362089	BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	43865
367873	BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	43865
367950	BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	43865
368267	BD Vacutainer® K2E 18.0mg Plus Blood Collection Tubes	43865
368274	BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	43865
368499	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
368841	BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	43865

Registered Office: Becton Dickinson UK Ltd. 1030 Eskdale Road, Wokingham, Berkshire, RG41 5TS. UK.
Registered No. 852702

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	362083	BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	43865
	362084	BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	43865
	364661	BD Vacutainer® K2E (EDTA) 3.6mg Plus Blood Collection Tubes	43865
	368843	BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	43865
	368856	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
	362072	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
	362085	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
	364664	BD Vacutainer® K2E (EDTA) 5.4mg Plus Blood Collection Tubes	43865
	368861	BD Vacutainer® K2E (EDTA) 7.2mg Plus Blood Collection Tubes	43865
	367836	BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	47588
	362086	BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	47588
	362087	BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	47588
	364663	BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	47588
	367858	BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	47588
	368270	BD Vacutainer® K3E 7.2mg Plus Blood Collection Tubes	47588
	368857	BD Vacutainer® K3E 5.4mg Plus Blood Collection Tubes	47588
	362073	BD Vacutainer® K3E 5.4mg Plus Blood Collection Tubes	47588
	362088	BD Vacutainer® K3E 5.4mg Plus Blood Collection Tubes	47588
	364662	BD Vacutainer® K3E 5.4mg Plus Blood Collection Tubes	47588
	368860	BD Vacutainer® K3E 7.2mg Plus Blood Collection Tubes	47588
	366547	BD Vacutainer® K3E 10.8mg Plus Blood Collection Tubes	47588
	366164	BD Vacutainer® K2E 7.2mg Plus Blood Collection Tubes	43865
	367941	BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	43865
	367924	BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	43865
	367978	BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	43865
IVDD Classification:	Non Annex II *In Vitro* Diagnostic Medical Device		
IVDD Conformity Assessment Route:	Annex III (excluding Annex III.6)		

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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.

List of Harmonized Standards:
EN ISO 13485:2012 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

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

PLACE, DATE OF ISSUE: Plymouth, 18th September 2018

Signature: _____

Brad Spring

Vice President, Regulatory Affairs

BD Life Sciences

Document Number: VR4310010

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VERSION HISTORY

Current Version Prepared By: Joseph Statham

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.