

EC DECLARATION OF CONFORMITY

Document Number: VR4310010

Manufacturer:	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom		
Authorised 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		
Products:	Catalogue number	Device name	GMDN Code
	365300	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
	365312	BD Vacutainer® K2E 18.0mg Plus Blood Collection Tubes	43865
	365900	BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	43865
	367386	BD Vacutainer® K2E 18.0mg 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
	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
	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
F-368856	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	43865
368834	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
366164	BD Vacutainer® K2E 7.2mg Plus Blood Collection Tubes	43865
367941	BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	43865
366547	BD Vacutainer® K3E 10.8mg Plus Blood Collection Tubes	47588
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
367924	BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	43865

	367978	BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	43865
	360073	BD Vacutainer® K2E (EDTA) 3.6mg Plus Blood Collection Tubes	43865
	360074	BD Vacutainer® K2E (EDTA) 7.2mg Plus Blood Collection Tubes	43865
	360075	BD Vacutainer® K2E (EDTA) 18.0mg Plus Blood Collection Tubes	43865
	368502	BD Vacutainer® K2E (EDTA) 5.4 mg Plus Blood Collection Tubes	43865
	367195	BD Vacutainer® K2E (EDTA) 10.8 mg Plus Blood Collection Tubes	43865
	367866	BD Vacutainer® K2E (EDTA) 10.8 mg Plus Blood Collection Tubes	43865
IVDD Classification:	Non Annex II <i>In Vitro</i> Diagnostic Medical Device		
IVDD Conformity Assessment Route:	Annex III (excluding Annex III.6)		

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 13485:2016 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. **BS EN ISO 11737-2:2020** 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 (R2009)** Standard Test Method for Drop Test of Loaded Containers by Free Fall **ASTM D999:2008 (R2015)**

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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: 13-January-2021

Signature: Kay A Taylor

Kay Taylor
Vice President, Regulatory Affairs
Life Science and IDS

Document Number: VR4310010

VERSION HISTORY

Current Version Prepared By: S. Chaudhry

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 catalog number F-368856 as per ACR PAS-2019-0021-00 “Repacking of SKUs as per tender requirements in Norway”.
E	Removed obsolete CAT No. 365314 per ACR PAS 000671-00. Updated ISO 13485 from 2012 to 2016.
F	Added Authorized Rep: BD Switzerland.
G	Added new catalog numbers, 360073, 360074, 360075 for prebarcoded product requested by European marketing, ACR PAS-2019-0075 Serialization of Product on Unit Level with Barcode (Universal Specimen Identification – USI).
H	Changed reference from EN ISO 11737-2:2009 to BS EN ISO 11737-2:2020 per BDVS-2020-04-29-113742. Added new catalog numbers for prebarcoded product requested by European marketing, ACR PAS-2019-0075 Serialization of Product on Unit Level with Barcode (Universal Specimen Identification – USI), 368502 & 367195. Updated to BD IDS-SM.
I	Added new catalog number for custom product requested by European marketing, ACR PAS-2020-0127 EDTA Tube with Red Cap Color, 367866; corrected typo in <i>Authorized Representative</i> name; reordered (all) and corrected (360073 & 360074 descriptions) catalog numbers per VS4310010 1.3 Product Catalogue Information; reordered non-harmonised standards per VS4310010 Appendix I.