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EC DECLARATION OF CONFORMITY

Document Number: VR4310010

Manufacturer:	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth,PL6 7BP, United Kingdom
Authorized Representative:	Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland
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	47592
368834	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	47592
365329	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	47592
365330	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	47592
365331	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	47592
365900	BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	47592
367525	BD Vacutainer® K2E (EDTA) 18.0mg Plus Blood Collection Tubes	47592
367838	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	47592
367386	BD Vacutainer® K2E 18.0mg Plus Blood Collection Tubes	47592
367839	BD Vacutainer® K2E 7.2mg Plus Blood Collection Tubes	47592
367864	BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	47592
362089	BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	47592
367873	BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	47592
367950	BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	47592
368274	BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	47592

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

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	368499	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	47592
	368841	BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	47592
	362084	BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	47592
	364661	BD Vacutainer® K2E (EDTA) 3.6mg Plus Blood Collection Tubes	47592
	368843	BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	47592
	F-368856	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	
	368856	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	47592
	362072	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	47592
	362085	BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	47592
	364664	BD Vacutainer® K2E (EDTA) 5.4mg Plus Blood Collection Tubes	47592
	368861	BD Vacutainer® K2E (EDTA) 7.2mg Plus Blood Collection Tubes	47592
	367836	BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	47588
	362086	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	47592
	367941	BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	47592
	367924	BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	47592
	360073	BD Vacutainer® K2E (EDTA) 7.2mg Plus Blood Collection Tubes	47592

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	360074	BD Vacutainer® K2E 7.2mg Plus Blood Collection Tubes	47592
	360075	BD Vacutainer® K2E (EDTA) 18.0mg Plus Blood Collection Tubes	47592
	368502	BD Vacutainer® K2E (EDTA) 10.8 mg Plus Blood Collection Tubes	47592
	367195	BD Vacutainer® K2E (EDTA) 10.8 mg Plus Blood Collection Tubes	47592
IVDD Classification:	Non Annex II *In Vitro* 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 regulatorypurposes **EN ISO 14971:2019** 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 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 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 - Part1: 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 **IEC 62366-1 Edition 1.1 2020-06** Medical devices - Application of usability engineering to medical devices

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

DATE OF ISSUE: 20-Dec-2022

DocuSigned by:
Anne Zavertnik
Signer Name: Anne Zavertnik
Signing Reason: I approve this document
Signing Time: 20-Dec-2022 | 10:38:53 PM GMT
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Signature: _____

Anne Zavertnik

Vice President, Regulatory Affairs

Integrated Diagnostic Solutions

Document Number: VR4310010

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VERSION HISTORY

Current Version Prepared By: Sharanya Jangiti

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 CAPA325553.
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. UpdatedISO 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 SpecimenIdentification – USI).
H	Removed catalogue numbers 365312, 362083, 362087, 368267, and367978 per ACR PAS-2021-0004. Updated VP to Anne Zavertnik.
I	Added new catalog numbers, 368502 & 367195 per ACR PAS-2019-0075 Serialization of Product on Unit Level with Barcode (Universal Specimen Identification – USI). Updated reference EN ISO 11137-1:2015 to EN ISO 11137-1:2015 AMD 2019 and EN ISO 11737-1:2018 to EN ISO 11737-1:2018 AMD 2021 per BDVS-2021-12-17-102739. Revised GMDN Code 43865 Evacuated blood collection tube IVD, K2EDTA to 47592 Evacuated blood collection tube IVD, anticoagulant per October GMDN revisions and obsoletions.
J	European Authorized Representative changed from BD Switzerland to BD Ireland. Change to the EU Authorized Representative name and address due to dissolution of the Swiss-EU mutual recognition agreement. Updated standards: 1. Updated reference to EN ISO 14971:2012 with EN ISO 14971:2019 where applicable 2. EN 62366:2008 has been withdrawn and superseded by 62366-1, Updated references to IEC 62366-1 to IEC 62366-1 Edition 1.1 2020-06. Moved to non-harmonized standard.
K	Removed reference to "EN ISO 18113-2:2011" per IDSQUALITYPLAN7720. Updated EU AR reference Name from "Becton Dickinson Ireland Ltd" to "Becton Dickinson Ireland Limited."