EC DECLARATION OF CONFORMITY

Document Number: VR4310006

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
365308	BD Vacutainer® LH 68 I.U. Plus Blood Collection Tubes	47589
367526	BD Vacutainer® LH 170 I.U. Plus Blood Collection Tubes	47589
367883	BD Vacutainer® LH 68 I.U. Plus Blood Collection Tubes	47589
367885	BD Vacutainer® LH 102 I.U. Plus Blood Collection Tubes	47589
368272	BD Vacutainer® LH 34 I.U. Plus Blood Collection Tubes	47589
368494	BD Vacutainer® LH (Lithium Heparin) 34 I.U. Plus Blood Collection Tubes	47589
368495	BD Vacutainer® LH 34 I.U. Plus Blood Collection Tubes	47589
368496	BD Vacutainer® LH 68 I.U. Plus Blood Collection Tubes	47589
368884	BD Vacutainer® LH (Lithium Heparin) 68 I.U. Plus Blood Collection Tubes	47589
368886	BD Vacutainer® LH (Lithium Heparin) 102 I.U. Plus Blood Collection Tubes	47589
368889	BD Vacutainer® LH 102 I.U. Plus Blood Collection Tubes	47589
369622	BD Vacutainer® NH 102 I.U. Plus Blood Collection Tubes	47589
367869	BD Vacutainer® NH (Sodium Heparin) 68 I.U. Plus Blood Collection Tubes	47592
367876	BD Vacutainer® NH (Sodium Heparin) 102 I.U. Plus Blood Collection Tubes	47592
369623	BD Vacutainer® NH 68 I.U. Plus Blood Collection Tubes	47592
360071	BD Vacutainer® LH 68 I.U. Plus Blood Collection Tubes	47589
360072	BD Vacutainer® LH (Lithium Heparin) 34 I.U. Plus Blood Collection Tubes	47589
360087	BD Vacutainer® LH 170 I.U. Plus Blood Collection Tubes	47589
367197	BD Vacutainer® LH (Lithium Heparin) 102 I.U. Plus Blood Collection Tubes	47589
367196	BD Vacutainer® NH (Sodium Heparin) 68 I.U. 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 regulatory purposes **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 AMD 2019** 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 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 18113-3:2011** In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009) **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 AMD 2021** 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 17141:2020** Cleanrooms and associated controlled environments – Biocontamination control **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 **IEC 62366-1 Edition 1.1 2020-06** Medical devices - Application of usability engineering to medical devices

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

DATE OF ISSUE: 18-Nov-2022

DocuSigned by:
Anne Zavertnik
Signer Name: Anne Zavertnik
Signing Reason: I approve this document
Signing Time: 18-Nov-2022 | 7:38:13 PM GMT
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Signature: _____

Anne Zavertnik

Vice President, Regulatory Affairs

Integrated Diagnostic Solutions

Document Number: VR4310006

VERSION HISTORY

Current Version Prepared By: K. Kenner Lemus

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	Updated EN ISO 13485:2012 to EN ISO 13485:2016 per ACR PAS-2019-0045 Technical File Update.
E	Added Authorized Rep: BD Switzerland; updated EN ISO 13485-2012 to 2016; updated authorized signature to Kay Taylor.
F	Added new catalog numbers,360071, 360072, 360087 for prebarcoded product requested by European marketing, ACR PAS-2019-0075 Serialization of Product on Unit Level with Barcode (Universal Specimen Identification – USI).
G	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), 367197 & 367196. Updated to BD IDS-SM.
H	Updated Standards: • Replaced EN ISO 14698-1:2003 and EN ISO 14698-2:2003 with standard EN 17141:2020 per CP BDVS-2021-01-18-102351. • Replaced EN ISO 18113-2:2011 with EN ISO 18113-3:2009 per IDSQUALITYPLAN7720. • Updated ref to EN ISO 11137-1:2015 to EN ISO 11137-1:2015 AMD 2019 and update ref to EN ISO 11737-1:2018 to EN ISO 11737-1:2018 AMD 2021 per BDVS-2021-12-17-102739 Removed GMDN code 47589 and replaced with 47592
I	Updated references to EN ISO 14971:2012, or ISO 14971:2007 with EN ISO 14971:2019. Update references to IEC 62366-1 to IEC 62366-1 Edition 1.1 2020-06. Note: Edition 1.1 is not currently harmonized. Modified European Authorized Representative 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. BSI Regulatory Statement accepting the appointment of BD Ireland as the EAR, dated 14 January 2022
J	Updated reference EN ISO 18113-3 2009 to EN ISO 18113-3:2011 per IDSQUALITYPLAN7720 Reviewed and correct the EU AR information (if incorrect) to include "Limited" in documentation that references the EU AR e.g.: Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland