

## EC DECLARATION OF CONFORMITY

Document Number: VR4380001

<b>Manufacturer:</b>	<b>Becton, Dickinson and Company</b> Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom																						
<b>Authorized Representative:</b>	Becton Dickinson Ireland Ltd. Donore Road Drogheda Co. Louth A92 YW26 Ireland																						
<b>Manufacturing Site(s):</b>	<b>Becton, Dickinson and Company</b> Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom																						
<b>Products:</b>	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Catalogue number</th> <th style="text-align: left;">Device name</th> </tr> </thead> <tbody> <tr> <td>364314</td> <td>BD Preset™ Arterial Blood Collection Syringe</td> </tr> <tr> <td>364327</td> <td>BD Preset™ Arterial Blood Collection Syringe</td> </tr> <tr> <td>364413</td> <td>BD Preset™ Arterial Blood Collection Syringe</td> </tr> <tr> <td>364415</td> <td>BD Preset™ Arterial Blood Collection Syringe</td> </tr> <tr> <td>364389</td> <td>BD Preset™ Eclipse™ Arterial Blood Collection Syringe</td> </tr> <tr> <td>364390</td> <td>BD Preset™ Eclipse™ Arterial Blood Collection Syringe</td> </tr> <tr> <td>364391</td> <td>BD Preset™ Eclipse™ Arterial Blood Collection Syringe</td> </tr> <tr> <td>364393</td> <td>BD Preset™ Eclipse™ Arterial Blood Collection Syringe</td> </tr> <tr> <td>364385</td> <td>BD Preset™ Eclipse™ Arterial Blood Collection Syringe</td> </tr> <tr> <td>364386</td> <td>BD Preset™ Eclipse™ Arterial Blood Collection Syringe</td> </tr> </tbody> </table>	Catalogue number	Device name	364314	BD Preset™ Arterial Blood Collection Syringe	364327	BD Preset™ Arterial Blood Collection Syringe	364413	BD Preset™ Arterial Blood Collection Syringe	364415	BD Preset™ Arterial Blood Collection Syringe	364389	BD Preset™ Eclipse™ Arterial Blood Collection Syringe	364390	BD Preset™ Eclipse™ Arterial Blood Collection Syringe	364391	BD Preset™ Eclipse™ Arterial Blood Collection Syringe	364393	BD Preset™ Eclipse™ Arterial Blood Collection Syringe	364385	BD Preset™ Eclipse™ Arterial Blood Collection Syringe	364386	BD Preset™ Eclipse™ Arterial Blood Collection Syringe
Catalogue number	Device name																						
364314	BD Preset™ Arterial Blood Collection Syringe																						
364327	BD Preset™ Arterial Blood Collection Syringe																						
364413	BD Preset™ Arterial Blood Collection Syringe																						
364415	BD Preset™ Arterial Blood Collection Syringe																						
364389	BD Preset™ Eclipse™ Arterial Blood Collection Syringe																						
364390	BD Preset™ Eclipse™ Arterial Blood Collection Syringe																						
364391	BD Preset™ Eclipse™ Arterial Blood Collection Syringe																						
364393	BD Preset™ Eclipse™ Arterial Blood Collection Syringe																						
364385	BD Preset™ Eclipse™ Arterial Blood Collection Syringe																						
364386	BD Preset™ Eclipse™ Arterial Blood Collection Syringe																						
<b>Classification:</b>	Class IIa																						
<b>Conformity Assessment Route:</b>	Conformity is established through application of the procedures described in Annex V and Annex VII of the European Medical Devices Directive 93/42/EEC.																						
<b>GMDN:</b>	58095- Blood gas syringe/needle, lithium heparin																						
<b>Notified Body:</b>	BSI Group The Netherlands B.V Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands																						
<b>CE Certificate Number:</b>	00362																						
<b>Date of issue of original CE Certificate:</b>	22 December 1994																						

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained under the premises of the manufacturer.

Document Number: VR4380001

**List of Harmonised 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 ISO 11737-2:2020** Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process **EN ISO 11137-1:2015 AMD 2019** Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices **EN ISO 11137-2:2015 AMD 2023** Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose **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 **EN 1041:2008+A1:2013** Information supplied by the manufacturer with medical devices **EN ISO 10993-1:2020** Biological evaluation of medical devices. Evaluation and testing within a risk management process **EN ISO 10993-5:2009** Biological evaluation of medical devices. Tests for in vitro cytotoxicity **EN ISO 10993-11:2009** Tests for systemic toxicity **EN ISO 10993-12:2012** Biological evaluation of medical devices - Part 12: Sample preparation and reference materials **EN ISO 10993-17:2009** Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances **EN ISO 10993-18:2009** Biological evaluation of medical devices - Part 18: Chemical characterization of materials **EN ISO 10993-23:2021** Biological evaluation of medical devices – Part 23: Tests for irritation **EN 556-1:2001** Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' **EN ISO 22442-3:2007** Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents **EN 20594-1:1993** Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986)

**List of Non-Harmonised Standards:**

**ISO 13485:2003** Medical devices -- Quality management systems -- Requirements for regulatory purposes **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 **EN ISO 6009:2016** Hypodermic needles for single use. Colour coding for identification **EN ISO 9626:2016** Stainless steel needle tubing for the manufacture of medical devices. Requirements and test methods **BS EN ISO 23908:2013\*** Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (ISO 23908:2011) **EN ISO 10993-2:2022** Biological Evaluation of Medical Devices - Part 2: Animal Welfare Requirements **EN ISO 10993-10:2023** Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization **EN ISO 10993-4:2017** Biological evaluation of medical devices. Selection of tests for interactions with blood **ISO 14001:2015** Environmental management systems - Requirements with guidance for use **EN ISO 7886-1:1997** Sterile hypodermic syringes for single use - Part 1: Syringes for manual use **EN ISO 7864:2016** Sterile hypodermic needles for single use. Requirements and test methods **EN ISO 80369-1:2010** Small bore connectors for liquids and gases in healthcare applications. General requirements **EN ISO 80369-20:2015** Small-bore connectors for liquids and gases in healthcare applications. Common test methods **ISO 594-2:1998** Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings **IEC 62366-1 Edition 1.1 2020-06** Medical devices Part 1: Application of usability engineering to medical devices **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 **EN ISO 22442-1:2015** Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management **EN ISO 22442-2:2015** Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling **EN ISO 11137-3:2017** Sterilisation of health care products – Radiation – part 3: Guidance on dosimetric aspects of development, validation and routine control **EN ISO 11737-1:2018 AMD 2021** Sterilization of medical devices – Microbial methods- Part 1 : Determination of a population of microorganisms on products

\* EN ISO 23908: 2013 is applicable to BD Preset™ Eclipse™ Arterial Blood Collection Devices only.

SIGNED FOR AND ON BEHALF OF:

Becton, Dickinson and Company

DATE OF ISSUE:

DocuSigned by:

*Anne Zavertnik*

**Signature:**



Signer Name: Anne Zavertnik

Signing Reason: I approve this document

Signing Time: 12-Sep-2023 | 2:32:56 PM BST

DC6A638A32E64A8A91F9D8DE330F0415

Anne Zavertnik

Vice President, Regulatory Affairs

Integrated Diagnostic Systems

Document Number: VR4380001

Document Number: VR4380001

<b><u>VERSION HISTORY</u></b>	
Current Version Prepared By: Amanda Ker	
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 to harmonised and non-harmonised standards list
D	Update to harmonised and non-harmonised standards list
E	Update to harmonised and non-harmonised standards list
F	Update harmonised EN ISO 11737-1:2006 to non-harmonised EN ISO 11737-1:2018 as per CAPA 325553.
G	Added Authorized Rep: BD Switzerland; changed Notified Body to BSI Netherlands; updated ISO13485-2012 to 2016; updated Authorized Signature to Kay Taylor.
H	Updated standards per CP BDVS-2021-01-18-102351: <ul style="list-style-type: none"> <li>• Replaced EN ISO 14698-1:2003 and EN ISO 14698-2:2003 with standard EN 17141:2020.</li> </ul> Corrected standard reference from EN 1041:2008 to EN 1041:2008+A1:2013. Changed authorized signature to Anne Zavertnik.
I	Updated ref to EN ISO 11137-1:2015 to EN ISO 11137-1:2015 AMD 2019, update ref to EN ISO 11737-1:2018 to EN ISO 11737-1:2018 AMD 2021, and update EN ISO 11737-2:2009 to EN ISO 11737-2:2020 per BDVS-2021-12-17-102739
J	Modified Section 2.1 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. Updated any references to EN ISO 14971:2012, or ISO 14971:2007 with EN ISO 14971:2019 Updated references to IEC 62366-1 to IEC 62366-1 Edition 1.1 2020-06
K	Added two country specific SKUs based on existing SKUs (364385 and 364386) per ACR PAS-2019-0097. The two new SKUs have a black needle shield and clear needle hub. Medical Device Change Notification Work Authorization Form was sent to notified body BSI on 21 Sept 2021 and a response received on 05 OCT 2021 confirming this is a non-substantial change and non-significant under MDR Article 120.3.
L	New standard EN ISO 10993-23:2021 added per BDVS_2022_09_26_140201.

Belliver Industrial Estate  
Belliver Way, Roborough  
Plymouth, PL6 7BP  
United Kingdom  
tel: +44(0)1752 701281  
www.bd.com



Advancing the  
world of health

	<p>Updated reference to EN ISO 10993-10:2013 to EN ISO 10993-10:2023 per BDVS-2023-07-13-152003.</p> <p>Updated reference to EN ISO 10993-2:2006 to EN ISO 10993-2:2022 per BDVS-2023-03-01-150036.</p> <p>Updated reference to EN ISO 11137-2:2015 to EN ISO 11137-2:2015 AMD 2023 per BDVS-2023-05-09-152705.</p> <p>Corrected reference to EN ISO 10993-1:2009 to EN ISO 10993-1:2020.</p>
--	---