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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 00362**

Issued To: **Becton, Dickinson and Company**
Belliver Industrial Estate
Belliver Way
Roborough, Plymouth
PL6 7BP
United Kingdom

In respect of:

The manufacture of sterile safety lancets, blood collection needles and syringes with pre-attached needles, to be used for the collection of blood for in vitro diagnostic examination.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1994-12-22** Date: **2019-11-28** Expiry Date: **2024-05-26**

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Supplementary Information to CE 00362

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Product Information Table

Number	Device Name	Intended Purpose per IFU
Class IIa		
MD 0106	BD Sentry Safety Lancet	Sterile, single-use, micro-collection lancet used to perform finger-stick punctures in adults and children for sampling capillary blood.
MD 0106	BD Preset & Preset Eclipse Arterial Blood Critical Care Collection Syringes (with pre-attached needle)	Sterile, single use device to be used for the collection, primary containment and preservation of blood specimens derived from the human body for the purposes of IVD examination
MD 0106	BD Vacutainer PrecisionGlide Multiple Sample Blood Collection Needle	Sterile single use medical device intended to be used for the sampling of venous blood derived from the human body for the purposes of for IVD examination
MD 0106	BD Vacutainer Eclipse Signal Blood Collection Needle	Sterile, single use device for the collection of multiple blood samples into evacuated blood collection tubes for the purpose of in vitro testing

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Number	Device Name	Intended Purpose per IFU
Class I		
MD 0106	BD Vacutainer Blood Collection Needle Holder	One Use Holder intended to be used in conjunction with the BD Vacutainer® range of blood collection needles, blood collection sets and luer adapter in order to facilitate the insertion of the needle into the patient's vein and to help guide the evacuated blood collection tube onto the non-patient (NP) end of the needle during the blood collection process.

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 00362**

Date: **2019-11-28**

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Date	Reference Number	Action
22 December 1994		First issue.
12 August 1997		Change of post code on address.
10 December 1997		Change of Notified Body (BSI) address.
22 February 2001		"with and without anticoagulant for diagnostic purposes" added to the scope, also removal of Griffith Microsciences (Somercotes) from sub-contractor list.
11 March 2004		Company name change to Becton Dickinson & Company, 5 year renewal, and addition of IBA S & I Limited, IBA Medisus S/A, Hepartex SA and Celsus Labs. Inc.
30 November 2009		Certificate renewal. Removal of 'Hepartex S.A', 'Celsus Laboratories, Inc.' and 'IBA S & I Limited' as subcontractors. Change of subcontractor name 'IBA Mediris S.A' to 'Sterigenics Belgium (Fleurus) SA and rewording of scope.
18 December 2014	8215528	Change of scope wording from 'syringe and needles' to 'sterile collection needles and syringes with pre-attached needles' Certificate renewal.

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
10 March 2017	8693238	Scope extension for sterile safety lancets (traceable to CE 583593). Addition of subcontractors HTL-Strefa, Poland as finished device supplier and Synergy Health Radeberg for gamma sterilisation of safety lancets.
05 March 2019	7779292	Traceable to NB 0086.
Current	9769232	Certificate Renewal. Addition of product information table. Addition of subcontractor BD Switzerland Sarl as EU Authorised Representative & HTL-Strefa S.A. Leczyca) for manufacture.

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

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EC DECLARATION OF CONFORMITY

Document Number: VR4380001

Manufacturer:	**Becton, Dickinson and Company** Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom
Authorized 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** 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
Classification:	Class IIa
Conformity Assessment Route:	Conformity is established through application of the procedures described in Annex V and Annex VII of the European Medical Devices Directive 93/42/EEC.
GMDN:	58095- Blood gas syringe/needle, lithium heparin
Notified Body:	BSI Group The Netherlands B.V Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
CE Certificate Number:	00362
Date of issue of original CE Certificate:	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.

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List of Harmonised 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 ISO 11737-2:2009** Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process **EN ISO 11137-1:2015** 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** 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** Information supplied by the manufacturer with medical devices **EN ISO 10993-1:2009** 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 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 10993-2:2006** Biological Evaluation of Medical Devices - Part 2: Animal Welfare Requirements **EN ISO 10993-10:2013** 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 **EN 62366-1:2015** Medical devices Part 1: Application of usability engineering to medical devices **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 **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** 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.

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

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

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SIGNED FOR AND ON BEHALF OF:	Becton, Dickinson and Company
DATE OF ISSUE:	09 September 2019

Signature: Kay A Taylor

Kay Taylor
Vice President, Regulatory Affairs
BD Diagnostics, Preanalytical Systems

Document Number: VR4380001

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Plymouth, PL6 7BP
United Kingdom
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Document Number: VR4380001

VERSION HISTORY

Current Version Prepared By: Pamela Sanecki

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.