By Royal Charter

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, 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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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	**Service(s) supplied**
Becton Dickinson Switzerland Sarl Terre Bonne Park - A4 Route de Crassier - 17 1262 Eysins Switzerland	**EU Representative**
HTL-Strefa S.A. Ul. Adamówek 7 95-035 Ozorków Poland	**Finished Device Supplier**
HTL-Strefa S.A. (Leczyca) UI. Lotnicza 21h 99-100 Leczyca Poland	**Manufacture**
Sterigenics Belgium (Fleurus) SA Zoning Industriel de Fleurus Avenue De L'Esperance Fleurus, Hainut B-6220 Belgium	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
Synergy Health Radeberg GmbH Juri-Gagarin Str. 15 D-01454 Radeberg Germany	**Gamma Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

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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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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.