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EC DECLARATION OF CONFORMITY

Document Number: VR4310003

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):	**HTL-Strefa S.A.** ul. Adamówek 7 95-035 Ozorków Poland
Products:	**Catalogue number** — **Device name** 369523 — BD Sentry™ Safety Lancet 369528 — BD Sentry™ Safety Lancet
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:	61578 – Manual blood lancing device, single use
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body No.: 2797
CE Certificate Number:	00362
Date of issue of original CE Certificate:	08 March 2012 (Original CE Certificate CE 583593)

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.

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 ISO 11737-2:2020** Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilization process, **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 medicaldevices, **EN ISO 11137-2:2015** Sterilization of health care products. Radiation. 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 of medical devices, **EN ISO 11607-1:2009+A1:2014** Packaging for terminally sterilized medical

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Registered No. 852702

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devices. Requirements for materials, sterile barrier systems and packaging systems, **EN ISO 10993-1:2009** Biological evaluation of medical devices. Evaluation and testing within a risk management process, **EN ISO 10993-2:2006** Biological evaluation of medical devices. Animal welfare requirements, **EN ISO 10993-3:2014** Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity, **EN ISO 10993-4:2009** Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood, **EN ISO 10993-5:2009** Biological evaluation of medical devices. Tests for in vitro cytotoxicity, **EN ISO 10993-11:2009** Biological evaluation of medical devices. Tests for systemic toxicity, **EN ISO 10993-12:2012** Biological evaluation of medical devices - Part 12: Sample preparation and reference materials, **EN ISO 10993-13:2010** Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices **EN ISO 10993-15:2009** Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys **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** Sterilisation of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilised medical devices

List of Non-Harmonised Standards:

ISO 14644-1:2015 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness, **ISO 10993-4:2017** Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood, **ISO 10993-6:2016** Biological evaluation of medical devices - Part 6: Tests for local effects after implantation, **EN ISO 10993-10:2013** Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization, **EN ISO 11737-1:2018 AMD 2021** Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products, **EN ISO 12048:2002** Packaging - Complete, filled transport packages - Compression and stacking tests using a compression tester, **EN 22248:2001** Packaging - Complete, Filled Transport Packages - Vertical Impact Test By Dropping, **EN 24180-2:2002** Guide to compilation of performance test schedules for complete, filled transport packages. Quantitative data, **EN 28768:2002** Packaging - Complete, Filled Transport Packages - Toppling Test., **EN ISO 2234:2007** Packaging -- Complete, filled transport packages and unit loads -- Stacking tests using a static load, **EN 60068-2-31:2010** Environmental testing. Tests. Test Ec. Rough handling shocks, primarily for equipment-type specimens

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 | 1:17:11 PM GMT
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Signature: _____

Anne Zavertnik

Vice President, Regulatory Affairs

Integrated Diagnostic Solutions

Document Number: VR4300003

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VERSION HISTORY

Current Version Prepared By: M. Tennen

REV.	Version Description
A	Transferred from QDMS to ECC – Version number remained 1
B	Transfer into new Medical Declaration of Conformity Template (MED-RA-001C). Replaced CE Certificate 583593 with CE Certificate 00362. Replaced obsolete GMDN code 37466 with 61578.
C	Update to harmonised and non-harmonised standards list
D	Added Authorized Rep: BD Switzerland; updated EN ISO 13485-2012 to 2016; changed authorized signature to Kay Taylor.
E	Updated standards per BDVS-2021-12-17-102739: • Replaced reference to EN ISO 11137-1:2015 with EN ISO 11137-1:2015 AMD 2019 • Replaced reference to EN ISO 11737-1:2006 with EN ISO 11737-1:2018 AMD 2021 and moved to Non-Harmonised standards table • Replaced reference to EN ISO 11737-2:2009 with EN ISO 11737-2:2020 Changed authorized signature to Anne Zavertnik.
F	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.
G	Amended for signature date correction from March 27, 2022 to new signature date.
H	Update EN ISO14971:2012 to EN ISO 14971:2019 per IDSQUALITYPLAN7591
I	Updated Authorized Representative: Becton Dickinson Ireland Ltd. to Becton Dickinson Ireland Limited