Becton, Dickinson and Company
17200 Laguna Canyon Rd
Irvine, CA 92618
USA
bd.com

DECLARATION OF CONFORMITY

We, Becton, Dickinson and Company, as the Product Owner, hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Medical Device Regulation (EU) 2017/745

Name and Address of Product Owner:
Becton, Dickinson and Company
17200 Laguna Canyon Rd.
Irvine, CA 92618
USA

Name and Address of Physical Manufacturer:
Measurement Specialties (Chengdu) Ltd.
China (Sichuan) Pilot Free Trade Zone, 368 Wulian First Road, Huangjia Street, Shuangliu District, Chengdu city, Sichuan Province, China

Medical Device(s):

Device Name	Model Number
ForeSight Sensor, Large Sensor	FSESL
ForeSight Jr Sensor, Medium Sensor	FSESM
ForeSight Jr Sensor, Small Sensor	FSESS
ForeSight Jr Sensor, Non-Adhesive Small Sensor	FSESNS

Risk Classification:
Class IIa per Rule 10, indent 3
(According to Annex VIII of MDR)

Quality Management System Certificate:
Certification Body: DNV Product Assurance AS
Certificate Number: 248918-2017-AQ-RGC-NA-PS
Issued date: 01 February 2025
Expiry date: 31 January 2028

CÔNG TY BECTON DICKINSON ASIA LIMITED
VĂN PHÒNG ĐẠI DIỆN TẠI TP HỒ CHÍ MINH
Võ Xuân Thắng
Giám đốc

Digitally signed by VPĐD BECTON DICKINSON ASIA LIMITED TẠI TP.HCM
Date: 2026.02.23 16:51:53 +07'00'

Standards Applied:

Standards/ Regulations	Title
EN ISO 13485:2021	Medical Devices – Quality Management Systems
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
ISO 20417:2021	Information supplied by the Manufacturer of Medical Devices

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Standards/ Regulations	Title
ISO 15223-1:2021	Medical Devices – Symbols to be used with information to be supplied by the Manufacturer- Part 1: General requirements
ISO 15223-2:2010	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol development, selection, and validation
IEC 60601-1:2022	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2020	Medical electrical equipment- Part 1-2: General Requirements for Safety-2. Collateral standard- electromagnetic compatibility-requirements and tests
IEC 60601-1-6:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance- Collateral Standard: Usability
IEC62366-1:2015/AMD1:2020	Medical devices - Application of usability engineering to medical devices
ASTM D4169-16 (2022)	Performance Testing of Shipping Containers and Systems
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-2:2022	Biological Evaluation of Medical Devices -Part 2: Animal Welfare Requirements
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-12: 2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 80601-2-85:2021	Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment
MEDDEV2.7.1 Rev. 4 (December 2016)	Guidelines on Medical Devices – Clinical Evaluation: A guide for Manufacturers and Notified Bodies
MDCG 2020-6: April 2020	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC.
MDCG 2020-7: April 2020	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
MDCG 2020-8: April 2020	Post-market clinical follow-up (PMCF) Evaluation Report Template. A guide for manufacturers and notified bodies
MDCG 2020-13: July 2020	Clinical evaluation assessment report template
DS/EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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Standards/ Regulations	Title
IEC 62474:2020	Material declaration for products of and for the electrotechnical industry - Edition 1.0
IEC 62321-1:2013	Determination of certain substances in electrotechnical products- Part 1: Introduction and overview- Edition 1.0
IEC 62321-2:2021	Determination of certain substances in electrotechnical products- Part 2: Disassembly, disjointment and mechanical sample preparation - Edition 1.0
IEC 62321-3-1:2013	Determination of certain substances in electrotechnical products – Part 3-1: Screening – Lead, mercury, cadmium, total chromium and total bromine by X-ray fluorescence spectrometry - Edition 1.0
IEC 62321-6:2015	Determination of certain substances in electrotechnical products- Part 6: Polybrominated biphenyls and polybrominated diphenyl ethers in polymers by gas chromatography - mass spectrometry (GC-MS) Edition 1.0
IEC 62321-7-2:2017	Determination of certain substances in electrotechnical products – Part 7-2: Hexavalent chromium – Determination of hexavalent chromium (Cr(VI)) in polymers and electronics by the colorimetric method-Edition 1.0

This declaration of conformity is valid from 13 February 2026.

Authorized Signatory:

Signed by:
Kevin Lam
Signer Name: Kevin Lam
Signing Reason: I approve this document
Signing Time: 13-Feb-2026 | 2:59:54 PM PST
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Kevin Lam,
Director, Regulatory Affairs