EU Declaration of Conformity (DoC)

We, **Devicor Medical Products, Inc.,** 300 E-Business Way, Fifth floor, Cincinnati, OH 45241, declare under our sole responsibility that the product to which this declaration relates is in conformity with the following standard(s) or other normative document(s) and proves the conformity of the designated product with the provisions of the European Medical Device Directive.

Provisions of the council directive 93/42/EEC for medical devices as amended and as transposed in national laws.

Products covered by this declaration:

Product Family**:** HydroMARK Breast Biopsy Site Markers.
See Appendix 1 for the complete list of products.

Harmonized Standards Applied:
See Appendix 2 for the complete list of harmonized standards applied.

Additional Information:

EU Authorized Representative:
CEpartner4U
Esdoornlaan 13, 3951 DB Maarn
The Netherlands

Notified Body:
TÜV SÜD PRODUCT SERVICE
GmbH, Ridlerstraße 65, 80339
MÜNCHEN, Germany

Notified Body Number: CE 0123

EC Certificate(s):
- G1 075302 0058, Rev 00: Annex II excluding (4)
- G7 075302 0056, Rev 01: Annex II (4)

Conformity Assessment Route: Annex
- G1 075302 0058, Rev 00: Annex II excluding (4)
- G7 075302 0056, Rev 01: Annex II (4)

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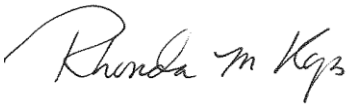
Date of first CE mark: 14 October 2014

Name: Rhonda M. Kops, RAC **Date:09 Feb 2021** **Place: Cincinnati, OH, USA**

Signature: **Title: Senior QRA Professional**



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Appendices

Appendix 1: List of Products:

Product Name	Product Code	Risk class/rule*
HydroMARk Breast Biopsy Site Marker	4010-01-08-T1	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-01-08-T3	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-01-08-T4	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-01-08-S1	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-03-09-T1	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-03-09-T3	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-04-09-T1	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-04-09-T3	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-04-09-T4	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-04-09-S3	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-01-11-T1	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-01-11-T3	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-01-11-T4	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-02-15-S1	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-02-15-S3	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-02-15-T1	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-02-15-T3	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-02-15-T4	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-03-15-T1-SHORT	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-03-15-T3-SHORT	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-02-18-T3	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-05-08-T1	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-05-08-T3	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-05-08-T4	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-05-10-T1	Class III/Rule 8
HydroMARk Breast Biopsy Site Marker	4010-05-10-T3	Class III/Rule 8

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HydroMARk Breast Biopsy Site Marker	4010-05-10-T4	Class III/Rule 8

**See risk classification and rule in Medical Device Directive 93/42/EEC, annex IX*

Appendix 2: List of Harmonized Standards:

A comprehensive list of applicable standards can be located in the Technical Documentation

Applied Standards		
Standard Number	**Issue Date**	**Standard Title**
COUNCIL DIRECTIVE 93/42/EEC	14 June 1993 and applicable amendments	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
2017/745	April 2017	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC Note: Transition period of 3 years
1907/2006	Dec 2006	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
MEDDEV 2.12-1 revision 8	Jan 2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
MEDDEV 2.7/1 revision 4	Jun 2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
MEDDEV 2.4/1 revision 9	Jun 2010	GUIDELINES RELATING TO THE APPLICATION OF THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES - Classification of medical devices
ISO 13485	2016	Medical Devices- Quality management Systems, Requirements for regulatory purposes
ISO 14971	2012	Medical Devices - Application of Risk Management to Medical Devices
ISO 11135:2014/Amd 1	2018	Sterilization of Health Care Products-Ethylene Oxide-Part I, Requirements for development, validation, and routine control of sterilization process for medical devices.
ISO 11138-1	2017	Sterilization of health care products-Biological Indicators-Part 1: General requirements.
ISO 11138-2	2017	Sterilization of health care products-Biological Indicators-Part 2: Biological indicators for ethylene oxide sterilization processes.
ISO 11138-7	2019	Sterilization of health care products -- Biological indicators -- Part 7: Guidance for the selection, use and interpretation of results.

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ISO 11737-1	2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
ISO 11737-2	2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
BS EN 556-1	2001/AC 2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
ISO 14937	2009	Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 10993-1	2018	Biological evaluation of medical devices, Part 1: Evaluating and testing within a risk management process.
ISO 10993-2	2006	Biological evaluation of medical devices - Part 2: Animal welfare requirements
ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5	2009	Biological evaluation of medical Devices Part 5: Tests for in vitro Cytoxicity
ISO 10993-6	2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
ISO 10993-7	2008/Cor 1:2009	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization.
ISO 10993-9	2009	Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-10	2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11	2017	Biological evaluation of medical Devices Part 11: Tests for systemic toxicity
ISO 10993-12	2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
ISO 10993-17	2002	Establishment of allowable limits for leachable substances
ISO 10993-18	2005	Biological evaluation of medical devices Part 18: Chemical characterization of materials
ISO 11607-1	2019	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2	2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN/ISO 14630	2012	Non-active surgical implants - General requirements
EN/ISO 16061	2015	Instrumentation for use in association with non-active surgical implants - General requirements
ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

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ISO 15223-2	2010	Medical devices-Symbols to be used with medical devices labels, labelling, and information to be supplied. Part 2: Symbols development, selection and validation.
ISO 7000:2014	2014	Graphical symbols for use on equipment-Registered symbols
BS EN 1041	2008 + A1:2013	Information supplied by the Manufacturer with Medical Devices
IEC 62366-1	2015	Medical devices - Application of usability engineering to medical devices
ISO 14644-1	2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
ISO 14155	2011/Cor 1:2011	Clinical investigation of medical devices for human subjects — Good clinical practice
ISO 80000-1	2009 /Cor 1: 2011	Quantities and units, General