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.

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Products covered by this declaration:
Product Family**: MammoMARK Site Identifier(s) and CorMARK Site Identifier(s)**
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):

- Full Quality Assurance System: G1 075302 0058 Rev. 00
- Design Examination: G7AO 075302 0048 Rev. 01 (Collagen Implants)

Conformity Assessment Route:

- MDD: Annex II, excluding (4) (Full Quality Assurance System)

Date of first CE mark: March 2012

Name: Rhonda M Kops, RAC

Date: 2021/03/24

Signature:

Title: Senior RAQA Professional

Place: Cincinnati, OH, USA

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Appendices

Appendix 1: List of Products:

Product Name	Product Code	Risk class/rule*	Basic UDI-DI #
MammoMARK® 11 Biopsy Site Identifier for use with 11G Mammotome® Probes	MAM3001	MDD: Class III/Rule 8 & 17	Not Available
MammoMARK2® 11 Biopsy Site Identifier for use with 11G Mammotome® Probes	MAM3002		
MammoMARK® 8 Biopsy Site Identifier for use with 8 Mammotome® Probes	MAM3008		
MammoMARK2® 11 Biopsy Site Identifier for use with Mammotome® MR 11G Probe/Targeting Set	MRM4002		
MammoMARK2® 8 Biopsy Site Identifier for use with Mammotome® MR 8G Probe/Targeting Set	MRM4008		
MammoMark® Biopsy Site Identifier - 8G (Bowtie shape marker)	MMK0801		
MammoMark® Biopsy Site Identifier - 8G (V shape marker)	MMK0802		
MammoMark® Biopsy Site Identifier - 10G (Bowtie shape marker)	MMK1001		
MammoMark Biopsy Site Identifier - 10G (V shape marker)	MMK1002		
14G CorMARK® Biopsy Site Identifier	MAM3014		

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Appendix 2: List of Harmonized Standards:

A comprehensive list of applicable standards can be located in the technical documentation.

Regulations and Standards	
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 (ISO 14971:2007, Corrected version 2007-10-01)
DIN EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006)
DIN EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
EN ISO 11137-3:2006	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects
EN ISO 11737-1:2015	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)
EN 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 (ISO 11737-2:2009)
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
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
ISO 10993-2:2006	Biological evaluation of medical devices - Part 2: Animal welfare requirements
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2003)
EN ISO 10993-4:2009	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-6:2009	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)
BS ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2009	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials(ISO 10993-12:2007)

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EN ISO 11607-1:2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2009)
EN ISO 11607-2:2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)
EN 62366:2015	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)
EN 1041:2008	Information Supplied by the Manufacturer with Medical Devices
ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness
ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments — Part 3: Test Methods
EN ISO 14644-4:2001	Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up
ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations
EN ISO 14630:2012	Non-active surgical implants - General requirements (ISO 14630:2008)
EN ISO 16061:2015	Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2008, Corrected version 2009-03-15)
EN ISO 22442-1:2015	Medical devices utilizing animal tissues and their derivatives. Application of risk management
EN ISO 22442-2:2015	Medical devices utilizing animal tissues and their derivatives. Controls on sourcing, collection and handling
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 (ISO 22442-2:2007)
ISO 14155:2011	Clinical investigation of medical devices for human subjects — Good clinical practice