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**: Mammotome revolve Dual Vacuum Assisted Breast Biopsy System**
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 (MDD-Class IIa, IIb & III devices)
- Product Quality Assurance System: G2S 075302 0059 (MDD-Class I sterile devices)

Conformity Assessment Route:

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

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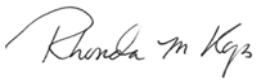
Date of first CE mark: January 2012

Name: Rhonda M. Kops, RAC

Date: 4 Dec 2020

Signature:

Title: Sr. Manager, Regulatory



Place: Devicor Medical Products, Inc, Cincinnati, OH, USA

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Appendices

Appendix 1: List of Products:

Product Name	Product Code	Risk class/rule*
Mammotome Control Module	MSCM1	MDD: Class IIa/Rule 11
Mammotome revolve ST Holster (for stereotactic x-ray guided procedures)	MSTH1	
Mammotome revolve Ultrasound Holster (for ultrasound guided procedures)	MHUSH1	
Mammotome revolve EX Holster (for ultrasound guided procedures)	MHEXH1	
8G Mammotome revolve Stereotactic Probe (9cm)	MST0809	
8G Mammotome revolve Stereotactic Probe (12cm)	MST0812	
8G Mammotome revolve Stereotactic Probe (15cm)	MST0815	
10G Mammotome revolve Stereotactic Probe (9cm)	MST1009	
10G Mammotome revolve Stereotactic Probe (12cm)	MST1012	
10G Mammotome revolve Stereotactic Probe (15cm)	MST1015	
8G Mammotome revolve Ultrasound probe (12cm)	MHUS08	
10G Mammotome revolve Ultrasound probe (12cm)	MHUS10	
8G Mammotome revolve EX Probe (9 cm)	MHEX08	
8G Mammotome revolve EX Probe with Sterile Sleeve (9 cm)	MHEX08S	
Specimen Management System, for Mammotome revolve 8G	MSMB1208	MDD: Class Is/Rule 1
Specimen Management System, for Mammotome revolve 10G	MSMB1210	
Mammotome revolve 8G Disposable Probe Guide for Lorad/Siemens/Giotto/Phillips/Fuji	MG08A	
Mammotome revolve 8G Disposable Probe Guide for GE	MG08B	
Mammotome revolve 10G Disposable Probe Guide for Lorad/Siemens/Giotto/Phillips/Fuji	MG10A	
Mammotome revolve 10G Disposable Probe Guide for GE	MG10B	
Mammotome revolve Remote Keypad	MHKEYP1	MDD: Class I/Rule 1 & 13
Mammotome revolve Footswitch	MFOOT1	
Mammotome revolve Cart	MCART1	
Mammotome revolve EX Holster Holder	MHEXHOLD1	

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Appendix 2: List of Harmonized Standards:

Standard	Year	Description
COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 and applicable amendments	1993	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
2017/745	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
2019/290/EU	2019	Waste Electrical and Electronic Equipment Directive (WEEE) - Establishing the format for registration and reporting of producers of electrical and electronic equipment to the register
2017/2102/EU	2017	Restriction of Hazardous Substances Directive (ROHS)
207/2012/EU	2012	Electronic instructions for use of medical devices
1907/2006	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
2014/30/EU	2014	Harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)
93/68/EEC	1993	CE Marking Directive
2014/53/EU	2014	Radio Equipment Directive
ETSI EN 300 330	2016 (V2.1.1)	Short Range Devices (SRD); Radio equipment in the frequency range
MEDDEV 2.12-1 revision 8	2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
MEDDEV 2.7/1 revision 4	2001	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
MEDDEV 2.4/1 revision 9	2010	GUIDELINES RELATING TO THE APPLICATION OF THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES - Classification of medical devices
MEDDEV 2.12/2 revision 8	2013	POST MARKET CLINICAL FOLLOW-UP STUDIES – A Guide for Manufacturers and Notified Bodies
ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes
BS EN ISO 14971	2012	Medical devices - Application of Risk Management to medical devices

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ISO 19011	2018	Guidelines for auditing management systems
ASQ Z1.4-2003 (R2018)	2018	Sampling Procedures and Tables for Inspection by Attributes (Z1.4)
ISO 11137-1	2006/Amd 2:2018	(Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices) Revision to 4.3.4 and 11.2
ISO 11137-2	2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
ISO 11737-1	2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
ISO 11737-2	2009	Sterilization of health care products - 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 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
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 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
IEC 60601-1	2005+AMD 1:2012 (3.1 Edition)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2 3rd edition	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

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IEC 62304	2006 +A1:2015	Medical device software - Software life-cycle processes - Amendment 1
IEC 62366-1	2015	Medical devices - Application of usability engineering to medical devices
IEC 60601-1-6	2010 +AMD1:2013	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
BS EN 1041	2008 + A1:2013	Information supplied by the Manufacturer with Medical Devices
ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements
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	2019	Graphical symbols for use on equipment-Registered symbols
ISO 14155	2011/Cor 1:2011	Clinical investigation of medical devices for human subjects — Good clinical practice
ISO 17664	2017	Processing of health care products – information to be provided by the medical device manufacturer for the processing of medical devices
EN 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
ISTA 2A	2012	Packaged-Products Weighing 150 LB (68 KG) Or Less
IEC 60601-1-9	2007/A1:2013	Medical electrical equipment Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design