EU Declaration of Conformity (DoC)-RED Directive

PRODUCT NAME: Mammotome revolve EX Holster
PRODUCT ID: MHEXH1
INCLUDED IN: *See Appendix 1*
TRANSMITTER FREQUENCY: 13.56 MHz
TRANSMITTER POWER: 100mW

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 Regulations.

Provisions of the council directive 2014/53/EU for medical devices as amended and as transposed in national laws.

Products covered by this declaration:

Product Family**: Mammotome revolve Dual Vacuum-Assisted Breast Biopsy System**
EC Certificate(s): G1 075302 0058, Rev 00 (Full Quality Assurance System)
See Appendix 1 for the complete list of products.

Harmonized Standards Applied:
See Appendix 2

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

Conformity Assessment Route: Annex II, excluding (4)

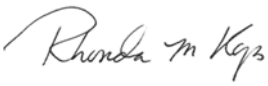
EU Declaration of Conformity (DoC)-RED Directive

Date of first CE mark: January 2012

Name: Rhonda Kops

Date: 2021-04-13

Signature:



Title: Sr. RAQA Professional

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Appendices

Appendix 1: List of Products:

Product Name	Module Containing Radio Equipment
Mammotome revolve EX Holster	MHEXH1

Appendix 2: List of Harmonized Standards:

Product complies to quality management system requirements and product specific harmonized standards for safety and performance. A full list of compliance harmonized standards is in the Technical Documentation file.