# 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**
*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 18 02 75302 045

**Conformity Assessment Route:** Annex II, excluding (4)

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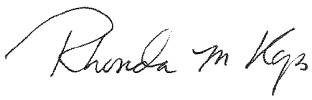
**Date of first CE mark**: January 2012

**Name:** Rhonda M. Kops, RAC

**Date:** September 4, 2020

**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:

| Number and Standard organization | Description of standard | Year |
|---|---|---|
| ETSI EN 300 330:2016 (V2.1.1) | RFID - Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz | 2016 |
| EN 301 489-1 V2.1.1 | ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU | 2016 |
| ISO 14971 | Medical Devices – Application of risk management to medical devices | 2012 |
| IEC 62304:2006+A1 | Medical device software - Software life-cycle processes IEC 62304:2006 | 2015 |
| 2014/53/EU | DIRECTIVE on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment | 2017 |
| 2014/30/EU | DIRECTIVE on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (repealing 2004/108/EC) | 2017 |