

## 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® Breast Biopsy System (Legacy)

#### EC Certificate:

- G1 075302 0058, Rev 00 (Full Quality Assurance System)
- G2S 075302 0059, Rev 00 (Product 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) (Full Quality Assurance System)
- Annex V (Product Quality Assurance System)

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Date of first CE mark: Feb 2012

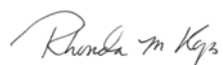
Name: Rhonda Kops

Date:

Place: Cincinnati, OH

Signature:

Title: Sr. RAQA Professional



### Appendices

#### Appendix 1: List of Products:

| Product Name   | REF#    | Risk class/rule   |
|--|---------|-------------------|
| Mammotome MR Targeting Sets short, 8G, 115mm length            | MRT08S  | Class IIa/ Rule 6 |
| Mammotome MR Targeting Set long, 8G, 145 mm length             | MRT08X  | Class IIa/ Rule 6 |
| Mammotome MR targeting set short, 11G, 115mm length            | MRT11S  | Class IIa/ Rule 6 |
| Mammotome MR Targeting Set long, 11G, 145mm length             | MRT11X  | Class IIa/ Rule 6 |
| Mammotome MR Universal Targeting Set, Short, 8G, 115mm         | MRU08S  | Class IIa/ Rule 6 |
| Mammotome MR Universal Targeting Set, Long, 8G, 145mm          | MRU08X  | Class IIa/ Rule 6 |
| Mammotome MR Universal Targeting Set, Short, 11G, 115mm        | MRU11S  | Class IIa/ Rule 6 |
| Mammotome MR Universal Targeting Set, Long, 11G, 145mm         | MRU11X  | Class IIa/ Rule 6 |
| Mammotome EX Probe and Vacuum Set, 8G                          | HH8BEX  | Class IIa/Rule 11 |
| Mammotome MR Bladeless Probe with Tube Set- Short, 8G (115cm)  | MRP08S  | Class IIa/Rule 11 |
| Mammotome MR Bladeless Probe with Tube Set- long, 8G (145cm)   | MRP08S  | Class IIa/Rule 11 |
| Mammotome MR Bladeless Probe with Tube Set- Short, 11G (115cm) | MRP08S  | Class IIa/Rule 11 |
| Mammotome Stereotactic Probe, 11G                              | MST11   | Class IIa/Rule 11 |
| Mammotome Stereotactic Probe, 14G                              | MST14   | Class IIa/Rule 11 |
| Mammotome EX Probe and Vacuum Set, 11G                         | HH11BEX | Class IIa/Rule 11 |

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|   |        |                          |
|---|--------|--------------------------|
| Mammotome MR Bladeless Probe with Tube Set- long, 11G (145cm) | MRP11X | Class IIa/Rule 11        |
| Mammotome Bladed Tip Stereotactic Probe, 11G                  | MST11B | Class IIa/Rule 11        |
| Mammotome Stereotactic Probe, 8G                              | MST8   | Class IIa/Rule 11        |
| Mammotome Vacuum Set  | MVAC1  | Class IIa/Rule 11        |
| Mammotome Probe Guide, 11G/Fisher                             | G011F  | Class 1 (sterile)/Rule 1 |
| Mammotome Probe Guide, 11G                                    | G011LF | Class 1/Rule 1           |
| Mammotome Probe Guide, 14G/Fisher                             | G014F  | Class 1/Rule 1           |
| Mammotome Probe Guide, 14G                                    | G014LF | Class 1/Rule 1           |
| Mammotome Probe Guide, 14G/Tru-Cut                            | G014U  | Class 1/Rule 1           |
| Mammotome Localization Guide, 20G                             | G020F  | Class 1/Rule 1           |
| Mammotome Probe Guide, 20G                                    | G020LF | Class 1/Rule 1           |
| Mammotome Probe Guide, 8G                                     | G08LF  | Class 1/Rule 1           |
| Mammotome Probe Guide, 8G                                     | G08U   | Class 1/Rule 1           |
| Mammotome Variable Aperture Sleeve, 8G                        | VAS08  | Class 1/Rule 1           |
| Mammotome Variable Aperture Sleeve, 11G                       | VAS11  | Class 1/Rule 1           |
| Mammotome Stereotactic Adapter                                | B1021  | Class 1/Rule 1           |
| Mammotome Forceps   | B1615  | Class 1/Rule 1           |
| Mammotome Lorad Equipment Drape                               | DL617  | Class 1/Rule 1           |
| Mammotome Probe Guide Holder                                  | G1621  | Class 1/Rule 1           |
| Mammotome Footswitch  | MFSW1  | Class 1/Rule 1           |
| Mammotome Remote Keypad                                       | MKEY1  | Class 1/Rule 1           |
| Mammotome Control Module MR Interlock System                  | MRLB1  | Class 1/Rule 1           |
| Mammotome Cart  | SCMC1  | Class 1/Rule 1           |
| Mammotome MR Cart Upgrade                                     | SCMC3  | Class 1/Rule 1           |

### 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.

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