



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 Regulations.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Products covered by this declaration:

Product Family:

- Mammotome Revolve™ Dual Vacuum-Assisted Biopsy System

See Appendix 1 for the complete list of products.

Certificate(s):

- G10 075302 0062 Rev. 00- EU Quality Management System Certificate (MDR)
 - Class IIa and Class IIb devices
- G11 075302 0063 Rev. 00- EU Quality Management System Certificate (MDR)
 - Class I devices in sterile, with measuring function or reusable surgical instruments

Harmonized Standards Applied:

See Appendix 2

Common Specifications Applied:

See Appendix 3

Additional Information:

EU Authorized Representative:

CEpartner4U
Esdoornlaan 13, 3951 DB Maarn
The Netherlands
SRN#: NL-AR-000000111

Notified Body:

TÜV SÜD PRODUCT SERVICE
GmbH, Ridlerstraße 65, 80339
MÜNCHEN, Germany
Notified Body ID Number: CE 0123

Conformity Assessment Route: Annex IX, Chapters I and III of MDR 2017/745

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DOCUMENT NUMBER: DC-001022

REVISION: 4.0

PAGES: Page 2 of 4

DOCUMENT OWNER: Josh Stamper

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Name: Gwendolyn Payne

Date: 2024-24-01

Signature:

A handwritten signature in black ink, appearing to read 'Gwendolyn Payne', written over a horizontal line.

Title: Director, Regulatory Affairs

Place: Cincinnati, Ohio, USA

Validity Date: 2029-24-01

Devicor Medical Products, Inc.
300 E-Business Way, Fifth Floor
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Reference Parent
Document:P1119

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Appendices

Appendix 1: List of Products:

Intended Purpose: To be used for the biopsy of percutaneous breast tissue procedure.

Product Name	Product Code	Risk class/rule*	Basic UDI-DI #
Mammotome Control Module	MSCM1	Class IIa/Rule 12	08419111AD02A000003322
Mammotome revolve ST Holster (for stereotactic x-ray guided procedures)	MSTH1		08419111AD02B000003322
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	Class IIa/Rule 6	08419111AD02C000003322
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		

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Specimen Management System, for Mammotome revolve 8G	MSMB1208	Class I sterile/ Rule 1	08419111AD02D000003322
Specimen Management System, for Mammotome revolve 10G	MSMB1210		
Mammotome revolve 8G Disposable Probe Guide for Lorad/Siemens/Giotto/Phillips/Fuji	MG08A		08419111AD02E000003322
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		

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.

Appendix 3: List of Common Specifications:

Number and Standard organization	Description of standard	Year
N/A	No common specifications apply to this device	N/A

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