



# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 075302 0058 Rev. 00**

**Manufacturer:**

**Devicor Medical Products, Inc.**

Fifth Floor  
300 E-Business Way  
Cincinnati OH 45241  
USA

**Product Category(ies): Control Modules, Holsters, Tissue Markers,  
Probes, Vacuum Sets and Targeting Sets  
for Breast Biopsy,  
Gamma Detection Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G1\\_075302\\_0058 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G1_075302_0058_Rev.00)

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2024-05-26

**Date,**

2020-09-14

Christoph Dicks  
Head of Certification/Notified Body