



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

EC Design-Examination Certificate

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

**No. G7 075302 0056 Rev. 01**

**Manufacturer:**

**Devicor Medical Products, Inc.**

Fifth Floor  
300 E-Business Way  
Cincinnati OH 45241  
USA

**Product:**

**Soft Tissue Implants  
Breast Biopsy Site Marker**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II 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:G7 075302 0056 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G7 075302 0056 Rev. 01)

**Report no.:**

713200267

**Valid from:**

2021-02-08

**Valid until:**

2024-05-26

**Date,**

2021-02-08

Christoph Dicks  
Head of Certification/Notified Body



# EC Certificate

EC Design-Examination Certificate

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

**No. G7 075302 0056 Rev. 01**

**Model(s):** HydroMARK Breast Biopsy Site Marker

**Parameter(s):**

Model Numbers:

4010-01-08-T1, 4010-01-08-T3, 4010-01-08-T4, 4010-01-08-S1

4010-03-09-T1, 4010-03-09-T3

4010-04-09-T1, 4010-04-09-T3, 4010-04-09-T4, 4010-04-09-S3

4010-01-11-T1, 4010-01-11-T3, 4010-01-11-T4

4010-02-15-S1, 4010-02-15-S3, 4010-02-15-T1, 4010-02-15-T3, 4010-02-15-T4

4010-03-15-T1 SHORT, 4010-03-15-T3 SHORT

4010-02-18-T3

4010-05-08-T1, 4010-05-08-T3, 4010-05-08-T4

4010-05-10-T1, 4010-05-10-T3, 4010-05-10-T4