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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

Report no.: 713200267

Valid from: 2021-02-08
Valid until: 2024-05-26

Date, 2021-02-08

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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

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