



Product Service

Certificate

No. Q5 075302 0057 Rev. 03

Holder of Certificate: **Devicor Medical Products, Inc.**
Fifth Floor
300 E-Business Way
Cincinnati OH 45241
USA

Certification Mark:



Scope of Certificate: Design and development, manufacture, service and distribution of sterile and non-sterile active surgical devices for breast nodes biopsy and location.
Design and development, manufacture and distribution of sterile and non-sterile non-active instruments and accessories for breast nodes biopsy and location.
Design and development, manufacture and distribution of devices for detection of gamma radiation used for oncological treatments.
Design and development, manufacture and distribution of soft tissue implants for breast and lymph node location with and without tissue of animal origin.
Warehousing, distribution and service for Active and Non-active medical devices used for oncological therapy.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5_075302_0057_Rev_03

Report No.: 713366355

Valid from: 2026-03-02

Valid until: 2029-03-01

Date, 2026-02-13

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Devicor Medical Products, Inc.**
Fifth Floor, 300 E-Business Way, Cincinnati OH 45241, USA

Design and development of sterile and non-sterile active surgical devices for breast nodes biopsy and location.

Design and development of sterile and non-sterile non-active instruments and accessories for breast nodes biopsy and location.

Design and development of devices for detection of gamma radiation used for oncological treatments.

Design and development of soft tissue implants for breast and lymph node location with and without tissue of animal origin.

Devicor Medical Products de Mexico S. de R.L. de C.V.

Parque Industrial Chilpancingo, Sor Juana Ines De La Cruz 20152
4-B, CP 22440 Tijuana, B.C., MEXICO

Manufacture of sterile and non-sterile active surgical devices for breast nodes biopsy and location.

Manufacture of sterile and non-sterile non-active instruments and accessories for breast nodes biopsy and location.

Manufacture of soft tissue implants for breast and lymph node location with and without tissue of animal origin.

Warehousing, distribution of soft tissue implants for breast and lymph node location without tissue of animal origin.

Devicor Medical Products Inc

Ste 120, 4750 Lake Forest Dr., Blue Ash OH 45242, USA

Warehousing, distribution for Active and Non-active medical devices used for oncological therapy.
Service of sterile and non-sterile active surgical devices for breast nodes biopsy and location.

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