



Certificate

No. Q5 056032 0108 Rev. 01

Holder of Certificate: **Synthes GmbH**
Eimattstrasse 3
4436 Oberdorf
SWITZERLAND

Certification Mark:



Scope of Certificate: **Design and Development, Manufacturing, Production and Distribution of Non-Active Implants as well as related Instruments and Software for Surgical Fixation, Correction and Regeneration of the Human Skeleton, Power Tools, Bone Replacement Products, Bone Cement and Related Mixing and Delivery Systems, and Non-Implantable Devices used to facilitate Implantations as well as servicing of Power Tools**

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 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:Q5 056032 0108 Rev. 01

Report No.: 713212856

Valid from: 2021-05-03
Valid until: 2024-02-10

Date, 2021-05-03



Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Synthes GmbH
Eimattstrasse 3, 4436 Oberdorf, SWITZERLAND

Central functions related to the quality management system
Design and Development of Non-Active Implants as well as related
Instruments and Software for Surgical Fixation, Correction and
Regeneration of the Human Skeleton, Power Tools, Bone
Replacement Products, Bone Cement and Related Mixing and
Delivery Systems, and Non-Implantable Devices used to facilitate
Implantations

Synthes Produktions GmbH
Eimattstrasse 3, 4436 Oberdorf, SWITZERLAND

Production of Non-Active Implants as well as related Instruments
for Surgical Fixation, Correction and Regeneration of the Human
Skeleton, Power Tools, Bone Replacement Products, Bone
Cement and Related Mixing and Delivery Systems, and Non-
Implantable Devices used to facilitate Implantations as well as
servicing of Power Tools

Synthes GmbH
Luzernstrasse 19-21, 4528 Zuchwil, SWITZERLAND

Central functions related to the quality management system
Design and Development of Non-Active Implants for Surgical
Fixation, Correction and Regeneration of the Human Skeleton,
Non-Implantable Devices used to facilitate Implantations

Synthes GmbH
Bohnackerweg 5, 2545 Selzach, SWITZERLAND

Warehousing, distribution and manufacturing related activities of
Non-Active Implants as well as related Instruments, Power Tools,
Bone Replacement Products, Bone Cement and Related Mixing
and Delivery Systems, and Non-Implantable Devices used to
facilitate Implantations

Synthes GmbH
Industriestrasse 28, 2545 Selzach, SWITZERLAND

Warehousing and manufacturing related activities of Non-Active
Implants as well as related Instruments, Power Tools, Bone
Replacement Products, Bone Cement and Related Mixing and
Delivery Systems, and Non-Implantable Devices used to facilitate
Implantations



Product Service

Certificate

No. Q5 056032 0108 Rev. 01

Synthes GmbH (DE)
Im Kirchenhürstle 4-6, 79224 Umkirch b. Freiburg, GERMANY

Production of non-active instruments for Surgical Fixation,
Correction and Regeneration of the Human Skeleton and Power
Tools

Synthes USA Products LLC
1302 Wrights Lane East, West Chester PA 19380, USA

Central functions related to the quality management system

Synthes USA Products LLC
1301 Goshen Parkway, West Chester PA 19380, USA

Design and Development of Non-Active Implants as well as related
Instruments for Surgical Fixation, Correction and Regeneration of
the Human Skeleton, Non-Implantable Devices used to facilitate
Implantations

Synthes USA Products LLC
1310 Goshen Parkway, West Chester PA 19380, USA

Central functions related to the quality management system

Synthes USA Products LLC
1230 Wilson Drive, West Chester PA 19380, USA

Design and Development of Bone Replacement Products, Bone
Cement and Related Mixing and Delivery Systems

Synthes USA Products LLC
1210 Ward Avenue, West Chester PA 19380, USA

Central functions related to the quality management system

DePuy Synthes Products Inc.
325 Paramount Drive, Raynham MA 02767, USA

Design and Development of Non-Active Implants as well as related
Instruments for Surgical Fixation, Correction and Regeneration of
the Human Skeleton, and Non-Implantable Devices used to
facilitate Implantations

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Synthes USA LLC
1101 Synthes Avenue, Monument CO 80132, USA

Distribution, warehousing and manufacturing related activities of Non-Active Implants as well as related Instruments for Surgical Fixation, Correction and Regeneration of the Human Skeleton, and Non-Implantable Devices used to facilitate Implantations

DePuy Synthes Products Inc.
1101 Synthes Avenue, Monument CO 80132, USA

Distribution, warehousing and manufacturing related activities of Non-Active Implants as well as related Instruments for Surgical Fixation, Correction and Regeneration of the Human Skeleton, and Non-Implantable Devices used to facilitate Implantations

Synthes USA LLC
1713 Jetstream Drive, Colorado Springs CO 80921, USA

Warehousing of Non-Active Implants as well as related Instruments for Surgical Fixation, Correction and Regeneration of the Human Skeleton, and Non-Implantable Devices used to facilitate Implantations

Innomedic GmbH
Forstdeichstr. 1-3, 76661 Philippsburg-Rheinsheim, GERMANY

Design and development of Software for Surgical Fixation, Correction and Regeneration of the Human Skeleton

Parameters: ./.