



Certificate

No. Q6 005434 0014 Rev. 03

Holder of Certificate: **Tornier SAS**
161 Rue Lavoisier
38330 Montbonnot-Saint-Martin
FRANCE

Certification Mark:



Scope of Certificate: **Contract manufacturing including:
manufacturing, packaging
and outsourced sterilization of
orthopaedic implants and
associated surgical instruments.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), 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.tivsud.com/ps-cert?q=cert:Q6 005434 0014 Rev. 03](http://www.tivsud.com/ps-cert?q=cert:Q6_005434_0014_Rev.03)

Report No.: 713225606

Valid from: 2022-02-18

Valid until: 2025-01-29

Date, 2022-02-18

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):

Tornier SAS
161 Rue Lavoisier, 38330 Montbonnot-Saint-Martin, FRANCE

Manufacturing of

- Orthopaedic joint implants for shoulder, elbow, ankle, hand, foot and wrist,
- Articular orthopaedic implants including pyrocarbon and associated ancillaries,
- Osteosynthesis implants,
- Associated surgical instruments,
- Computer aided systems for orthopaedic surgery

Tornier SAS - Montbonnot

176 Rue Lavoisier, 38330 Montbonnot-Saint-Martin, FRANCE

Manufacturing of

- Orthopaedic joint implants for shoulder, elbow, ankle, hand, foot and wrist,
- Articular orthopaedic implants including pyrocarbon and associated ancillaries,
- Osteosynthesis implants,
- Associated surgical instruments

Tornier SAS - Montbonnot

385 Rue Lavoisier, 38330 Montbonnot-Saint-Martin, FRANCE

Manufacturing of

- Associated surgical instruments

Tornier SAS - Grenoble

Parc d'activités Polytec, 20 Rue des Berges, 38000 Grenoble, FRANCE

Manufacturing of

- Articular orthopaedic implants including pyrocarbon