



Certificate

No. Q8 109252 0002 Rev. 01

Holder of Certificate: **Hofmann S.r.l.**

Via Carlo Carrà 19
20900 MONZA MB
ITALY

Facility(ies):

Hofmann S.r.l.

Via Carlo Carrà 19, 20900 MONZA MB, ITALY

See Scope of Certificate

Certification Mark:



Scope of Certificate:

The provision of contract design and contract manufacturing services for orthopedic prosthesis, orthopedic fixation, osteosynthesis medical devices, spinal implants and related instruments. The provision of contract repair services of non-active and non-implantable medical devices surgical instruments for orthopedic prosthesis, orthopedic fixation, osteosynthesis medical devices and spinal implants.

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

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:Q8_109252_0002_Rev_01

Report No.: ITA200220003766

Valid from: 2024-09-03

Valid until: 2026-01-14

Date, 2024-09-03



Christoph Dicks
Head of Certification/Notified Body