



Certificate

No. Q6 091338 0003 Rev. 01

Holder of Certificate: **Ortho Solutions Sdn Bhd**
2821, Tingkat Perusahaan 5A
Prai Industrial Estate
13600 Prai, Penang
MALAYSIA

Facility(ies): Ortho Solutions Sdn Bhd
2821, Tingkat Perusahaan 5A, Prai Industrial Estate, 13600 Prai,
Penang, MALAYSIA

Manufacturing of Non-Sterile Orthopedic Implants and Instruments

Certification Mark:



Scope of Certificate: **Manufacturing of Non-Sterile
Orthopedic Implants and
Instruments**

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

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.tuvsud.com/ps-cert?q=cert:Q6_091338_0003_Rev_01

Report No.: MYQMH0121001-721426984

Valid from: 2021-06-21
Valid until: 2024-06-12

Date, 2021-06-21



Christoph Dicks
Head of Certification/Notified Body