



# Certificate

No. Q6 091338 0003 Rev. 02

**Holder of Certificate:** **Ortho Solutions Sdn Bhd**

2821, Tingkat Perusahaan 5A  
Prai Industrial Estate  
13600 Prai, Penang  
MALAYSIA

**Certification Mark:**



**Scope of Certificate:** **Manufacturing of Non-Sterile Orthopedic Implants and 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.tuvsud.com/ps-cert?q=cert:Q6 091338 0003 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q6 091338 0003 Rev. 02)

**Report No.:** 5819458-721432516

**Valid from:** 2023-10-23

**Valid until:** 2026-10-22

**Date,** 2023-10-23

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):**

**Ortho Solutions Sdn Bhd**

2821, Tingkat Perusahaan 5A, Prai Industrial Estate, 13600 Prai,  
Penang, MALAYSIA

Manufacturing of Non-Sterile Orthopedic Implants and Instruments

**Ortho Solutions Sdn Bhd**

11A, 15, Lorong Saga Jaya 6, Taman Perindustrian Saga Jaya,  
13600 Prai, Penang, MALAYSIA

Manufacturing of Non-Sterile Orthopedic Implants and Instruments

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