



# Certificate

No. Q5 052905 0138 Rev. 01

**Holder of Certificate:** **Mathys AG Bettlach**  
**(Translation according to the competent**  
**Swiss Commercial Register:**  
**Mathys SA Bettlach, Mathys Ltd Bettlach)**  
Robert Mathys Strasse 5  
2544 Bettlach  
SWITZERLAND

**Certification Mark:**



**Scope of Certificate:** **Design and development, production and distribution of non-active implants and related instruments for orthopaedics as well as bone replacement products and related 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, 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 052905 0138 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_052905_0138_Rev.01)

**Report No.:** 713217573

**Valid from:** 2021-11-01

**Valid until:** 2024-10-31

**Date,** 2021-10-29



Christoph Dicks  
Head of Certification/Notified Body

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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):

Mathys AG Bettlach (Translation according to the competent Swiss  
Commercial Register: Mathys SA Bettlach, Mathys Ltd Bettlach)  
Robert Mathys Strasse 5, 2544 Bettlach, SWITZERLAND

Top Management / Quality Management / Administration,  
Regulatory Affairs, Design and Development, Production and  
Process Controls (Metal & Plastic based processing (implants &  
instruments) & resorbable synthetic bone substitutes), Product  
Documentation, Purchasing Controls incl. Verification of  
Purchased Devices, Corrective and Preventive Actions incl. Post-  
Market Surveillance, Post Market Clinical Follow-up (PMCF),  
Clinical Affairs

Mathys Orthopädie GmbH  
An den Trillers Büschen 2, 07646 Mörsdorf, GERMANY

Design and Development, Production and Process Controls  
(Ceramic based processing (implants)), Product Documentation,  
Purchasing Controls incl. Verification of Purchased Devices

Mathys Orthopädie GmbH  
Michael-Faraday-Straße 5, 07629 Hermsdorf, GERMANY

Design and Development, Production and Process Controls (Metal  
based processing (implants & instruments)), Product  
Documentation, Purchasing Controls incl. Verification of  
Purchased Devices

Mathys (Schweiz) GmbH  
Robert Mathys Strasse 5, 2544 Bettlach, SWITZERLAND

Sales and Distribution for national market in Switzerland.

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