ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 043036 0026 Rev. 00

Holder of Certificate: **WITTENSTEIN intens GmbH**
Walter-Wittenstein-Strasse 1
97999 Igersheim
GERMANY

Facility(ies):
WITTENSTEIN intens GmbH
Walter-Wittenstein-Strasse 1, 97999 Igersheim, GERMANY

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate:
Design and Development, Production and Distribution of Implantable Actuator Systems for Limb Lengthening and Corrections as well as for Stabilization and Reconstruction of Skeletal Bones;
Distribution of Drive Components for Heart Assist Systems

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, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713163162

Valid from: 2019-11-01
Valid until: 2022-10-31

Date, 2019-10-24

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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