ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. I1 17 07 43036 021

Manufacturer:

WITTENSTEIN intens GmbH
Walter-Wittenstein-Strasse 1
97999 Igersheim
GERMANY

WITTENSTEIN | intens

Product:

Implantable Actuator Systems for Limb Lengthening and Corrections

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. See also notes overleaf.

Report No.: 713112116

Valid from: 2017-08-01
Valid until: 2022-07-31

Date, 2017-07-31

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Facility(ies):

WITTENSTEIN intens GmbH
Walter-Wittenstein-Strasse 1, 97999 Igersheim, GERMANY

Design Facility(ies):

WITTENSTEIN intens GmbH
Walter-Wittenstein-Strasse 1, 97999 Igersheim, GERMANY

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