



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 11 07 43036 014

Manufacturer:**WITTENSTEIN intens GmbH****WITTENSTEIN**

intens

Walter-Wittenstein-Straße 1
97999 Igersheim
GERMANY

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.: 71384585**Valid from:** 2011-09-21
Valid until: 2016-07-31**Date,** 2011-09-22

Hans-Heiner Junker

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