



Product Service

# EC - CERTIFICATE

## Full Quality Assurance System

(Annex 2, section 3 of the Directive 90/385/EEC on Active Implantable Medical Devices)

No. I1 06 08 43036 006

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

Walter-Wittenstein-Straße 1  
97999 Igersheim  
GERMANY

**Facility(ies):**

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

WITTENSTEIN AG  
Walter-Wittenstein-Straße 1, 97999 Igersheim, GERMANY

**Product:**

**Fully Implantable, Self-Contained,  
Active Intramedullary Distraction  
Device for Limb Lengthening  
Self-contained, Active Implants  
for Callus Distraction**

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 products / product families according to Annex 2, section 3 of the Directive 90/385/EEC on Active Implantable Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of the product an additional Annex 2.4 certificate is mandatory. See also notes overleaf.

**Report no.:** 71311454

**Valid until:** 2011-07-31

**Date,** 2006-09-22

Reiner Krumme



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 90/385/EEC concerning Active Implantable Medical Devices with identification no. 0123.

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