



Product Service

EC Design Examination Certificate

(Annex 2, section 4 of the Directive 90/385/EEC on
Active Implantable Medical Devices)

No. I7 08 04 43036 011

Manufacturer: **WITTENSTEIN intens GmbH**

Walter-Wittenstein-Straße 1
97999 Igersheim
GERMANY

Product: **Implantable (Bone) Actuator Systems;
Fully implantable, Active Intramedullary Distraction
Device for Limb Lengthening and Correction**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the aforementioned devices according to Annex 2, section 4 of the Directive 90/385/EEC on Active Implantable Medical Devices. This design of the devices conforms to the provisions of this Directive. For marketing of the product an additional Annex 2.3 certificate is mandatory. See also notes overleaf.

Report No.: 71334774

Valid until: 2013-04-15



Date, 2008-08-20

Hans-Heiner Junker

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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No. I7 08 04 43036 011

Model(s): FITBONE[®] SAA 1340
FITBONE[®] SAA 1360

Parameters: ./.

Facility(ies): WITTENSTEIN intens GmbH
Walter-Wittenstein-Straße 1, 97999 Igersheim, Germany

Design Facility(ies): WITTENSTEIN intens GmbH
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