

# EC Design Examination Certificate



No.: I7 03 04 43036 005

according to Annex 2, section 4 of Council Directive 90/385/EEC for active implantable medical devices for

**Wittenstein intens GmbH**  
**Walter-Wittenstein-Straße 1**

**D-97999 Igersheim**

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

**Model:** Fitbone SAA 1340  
Fitbone SAA 1360

The above mentioned product fulfills the essential requirements of the Directive.

This certificate is based on the examination of the submitted technical design documentation (design dossier). For detailed results of the examination of the design dossier see

Test report no.: 70006188.

This certificate is valid until 2008-04-15.

Released with the above mentioned certificate number by the Certification Body of TÜV PRODUCT SERVICE.



Department: MUC AMI / rt / dk  
Date: 2003-04-16

TÜV PRODUCT SERVICE GMBH is Notified Body according to Council Directive 90/385/EEC for active implantable medical devices, notified by publication in the Official Journal of the EC No. C 209/8 dated Aug. 3, 1993 with identification no. 0123.