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

TÜV SÜD
Product Service

CERTIFICATE

No. Q1N 07 10 43036 009

Holder of Certificate: **WITTENSTEIN intens GmbH**

WITTENSTEIN intens

Walter-Wittenstein-Straße 1
97999 Igersheim
GERMANY

Facility(ies):

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

Certification Mark:

TÜV SÜD ISO 13485:2003

Scope of Certificate:

Design and Development, Production and Distribution of Fully Implantable, Self-Contained Active Intramedullary Distraction Devices for Limb Lengthening and of Self-Contained, Active Implants for Callus Distraction

Applied Standard(s):

EN ISO 13485:2003
Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke
EN ISO 13485:2003
Medical Devices - Quality Managment Systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 71326752

Valid until: 2010-1031

Date, 2007-11-01

Reiner Krumme

TÜV 318208

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ZLG

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