

Treu – Instrumente GmbH

*Altentalstraße 6 – 10 * D – 78532 Tuttlingen *

DECLARATION OF CONFORMITY

Declaration of Conformity :

Valid until 30.04.2010

Name of the manufacturer : Treu – Instrumente GmbH

Name and address : Treu – Instrumente GmbH
Altentalstrasse 6 – 10
D – 78532 Tuttlingen

Product group : Surgical instruments, implants for osteosyntheses and prosthesis
Orthopaedic hip – and knee-implants
battery driven units in accordance to the actual product listing of
the Treu-Instrumente GmbH for Class I. / II.a and II.b products

Classification : Class I products in accordance with Annex IX, Rule 1 / 6
Class II.a products in accordance with Annex IX, Rule 9 / 11
Class II.b products in accordance with Annex IX, Rule 8
of the 93/42 EEC

Chosen conformity assessment procedure : in accordance with Annex II.3 and VII for
Class I. IIa. / IIb. Products of the council directive , No. 93/42 EEC on Medical Devices.

We hereby declare that the above-mentioned products fulfil the directive of the Council
Directive 93/42 EEC on medical devices. The entire respective documentation is kept on
the premises of the manufacturer.

Applied standards : EN 556/EN 552/ISO 11134/ISO 10993 part 1.5.11/EN980/
ISO 15223/EN 1041/ISO 14971/EN 868 part 1/EN60601-1-2/
EN 60601-1+A1+A2/ISO 16142 / MED.UMW
Guidelines on a Medical Device Vigilance System , MEDDEV
2.12/1, Feb.98 , Rev , European Commission DG III

Notified body : TÜV PRODUCT SERVICE GMBH – code number 0123
Ridlerstraße 65 , D – 80339 Munich

ISO 9001:2000 Certificate : Reg.No. 12 100 28573 TMS valid until 30.04.2010

EN ISO 13485:2003 Certificate : Reg.No. Q1N 09 08 32964 019 valid until 30.04.2010

EC-Certificate Annex II.3 : Reg.No. G1 06 02 32964 011 valid until 31.05.2011

Class II.a products

EC-Certificate Annex II.3 : Reg.No. G1 09 08 32964 018 valid until 08.07.2013

Class IIa and II.b products Under condition of regular inspection

Beginning of application of the CE – mark CE 0123 : ab 01.07.1996

Place , Date : D – 78532 Tuttlingen 09.11.09

Signature :..... Name and position : Quality Manager Jörg Kapp

Author : Jörg Kapp

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