ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 003228 0001 Rev. 01

Manufacturer:

Signature Orthopaedics Europe Limited
Unit A
IDA Business & Technology Park
Garrycastle
Athlone
N37 DY26 Co. Westmeath
IRELAND

Product Category(ies): **Cemented and cementless knee and hip systems, bone cement delivery system, trials implants, spinal implants, osteosynthesis implants, non-resorbable soft tissue fixation implants, radio opaque markers, and related instrumentation including reusable, single use sterile, non active measuring used during implantation surgery and those connected to active and non-active medical devices.**

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 devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713177151

Valid from: 2020-03-24
Valid until: 2024-05-26

Date, 2020-03-24
Digitally signed by Chicu Natalia
Date: 2024.02.02 17:12:33 EET
Reason: MoldSign Signature
Location: Moldova

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany