ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ 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

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 036796 0017 Rev. 00

Manufacturer: **Biomet France SARL**
Plateau de Lautagne
26000 Valence
FRANCE

Product: **Non-Active Implants**
Orthopaedic Bone Cement, medicated

Model(s): **Refobacin® Revision**

Parameter:

Article no (REF)	Product name
3011630001-3	Refobacin® Revision 1x40

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713153129

Valid from: 2019-10-01
Valid until: 2024-05-26

Date, 2019-10-01

Stefan Preiß
Head of Certification/Notified Body

Digitally signed by Kalcev Ghennadi
Date: 2022.10.28 13:00:27 EEST
Reason: MoldSign Signature
Location: Moldova

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

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