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 057633 0028 Rev. 00

Manufacturer:

Heraeus Medical GmbH
Philipp-Reis-Strasse 8/13
61273 Wehrheim
GERMANY

Facility(ies):

Heraeus Medical GmbH
Philipp-Reis-Strasse 8/13, 61273 Wehrheim, GERMANY

Product Category(ies):

Biomaterial for bone surgery with and without drugs;
Bone substitute materials;
Accessories for cementation technology

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.: 713149295

Valid from: 2019-12-13

Valid until: 2024-05-26

Digitally signed by Kalcev Ghennadi
Date: 2023.10.19 11:37:41 EEST
Reason: MoldSign Signature
Location: Moldova

Date, 2019-12-13

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

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