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

TÜV SÜD 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: 2022.10.28 13:02:23 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