



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 16 03 57633 018

Manufacturer:

Heraeus

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.:

713078477

Valid from:

2016-11-30

Valid until:

2021-11-29



Date, 2016-09-07

S. Preiß

Stefan Preiß

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

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