



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 029547 0027 Rev. 01

Manufacturer: **UEBE MEDICAL GmbH**
Zum Ottersberg 9
97877 Wertheim
GERMANY

**Product Category(ies): Fertility Monitors, Medical Fertility Apps,
Medical Thermometers,
Blood Pressure Monitors and Nebulizers**

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.: 713169994

Valid from: 2020-03-25
Valid until: 2024-05-26

Date, 2020-03-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17



Product Service

Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 029547 0030 Rev. 00

Manufacturer: **UEBE MEDICAL GmbH**
Zum Ottersberg 9
97877 Wertheim
GERMANY

This List of Sites is only **G1 029547 0027 Rev. 01**
valid in combination with the
following EC Certificate (MDD):

The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EC Certificate pursuant to the Directive 93/42/EEC (MDD) concerning medical devices.

Report No.: 713169994

Valid until: 2024-05-26

Issue Date: 2020-04-02

(Randolph Köhler)
PS-MHS-FA-0 – Foreign Affairs



Product Service

Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 029547 0030 Rev. 00

Sites:

UEBE MEDICAL GmbH
Zum Ottersberg 9, 97877 Wertheim, GERMANY

UEBE MEDICAL GmbH
Zum Schlag 18, 97877 Wertheim, GERMANY

Uebe Medical GmbH
Bürgermeister-Kuhn-Str. 20 & 22, 97900 Kulsheim, GERMANY