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 075707 0030 Rev. 01

**Manufacturer:**

**GE Healthcare Austria GmbH & Co OG**
Tiefenbach 15
4871 Zipf
AUSTRIA

**Facility(ies):**

GE Healthcare Austria GmbH & Co OG
Tiefenbach 15, 4871 Zipf, AUSTRIA

**Product Category(ies):**

**Diagnostic Ultrasound Systems, related Probes and Standalone Software for Ultrasound-Image Processing**

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.:** 713142159

**Valid from:** 2019-04-01
**Valid until:** 2024-03-31

**Date,** 2019-01-02

Stefan Preiß

Digitally si
Date: 2022
Reason: M
Location: M


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

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