





## **Certificate**

No. Q5 075707 0058 Rev. 02

Holder of Certificate: GE Healthcare Austria GmbH & Co OG

Tiefenbach 15 4871 Zipf AUSTRIA

Facility(ies): GE Healthcare Austria GmbH & Co OG

Tiefenbach 15, 4871 Zipf, AUSTRIA

Design and Development, Production and Distribution of Diagnostic Ultrasound Systems, Probes and Standalone Software

for Ultrasound-Image Processing

**Certification Mark:** 



Scope of Certificate: Design and Development, Production

and Distribution of Diagnostic Ultrasound Systems, Probes and Standalone Software

for Ultrasound-Image Processing

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: <a href="https://www.tuvsud.com/ps-cert?q=cert:Q5-075707-0058-Rev.02">www.tuvsud.com/ps-cert?q=cert:Q5-075707-0058-Rev.02</a>

**Report No.:** 713202497

 Valid from:
 2021-11-20

 Valid until:
 2024-04-23

Date, 2021-11-11 Christoph Dicks

Head of Certification/Notified Body