



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: www.tuvsud.com/ps-cert?q=cert:Q5 075707 0058 Rev. 02

Report No.: 713202497

Valid from: 2021-11-20
Valid until: 2024-04-23

Date, 2021-11-11

Christoph Dicks
Head of Certification/Notified Body