ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Digitally signed by Chicu Natalia
Date: 2024.02.24 09:04:42 EET
Reason: MoldSign Signature
Location: Moldova

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

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