



Certificate

No. Q5 020505 0021 Rev. 00

Holder of Certificate: **TOMTEC Imaging Systems GmbH**

Edisonstrasse 6
85716 Unterschleissheim
GERMANY

Facility(ies):

TOMTEC Imaging Systems GmbH
Edisonstrasse 6, 85716 Unterschleissheim, GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Production, Distribution, Installation and Service of Medical Software for Diagnostic Image and Information Processing as well as Image Management Software

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). See also notes overleaf.

Report No.:

713139766

Valid from:

2019-02-20

Valid until:

2022-02-19

Date,

2019-02-20

Stefan Preiß