



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 16 02 20505 017

**Manufacturer:** TOMTEC IMAGING SYSTEMS GmbH

Edisonstraße 6  
85716 Unterschleissheim  
GERMANY



**Facility(ies):** TOMTEC IMAGING SYSTEMS GmbH  
Edisonstraße 6, 85716 Unterschleissheim, GERMANY

**Product Category(ies):** Data Analysis Software  
for Digital Medical Data

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.:** 713072415

**Valid from:** 2016-02-07  
**Valid until:** 2021-02-06

**Date,** 2016-01-19

Hans-Heiner Junker



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