Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 037489 0056 Rev. 00**

**Manufacturer:**

**Brainlab AG**
Olof-Palme-Straße 9
81829 München
GERMANY

**Facility(ies):**

Brainlab AG
Olof-Palme-Straße 9, 81829 München, GERMANY

**Product Category(ies):**

**Navigation Systems, Surgical Instruments, Medical Data Information Terminals and Medical Software for**
**- Image Processing**
**- Image Guided Surgery**
**- Neurosurgery**
**- Cranio-Maxillo-Facial Surgery**
**- Ear-Nose-Throat Surgery**
**- Orthopedic Surgery**
**- Spine/ Trauma Surgery**
**- Instrument Positioning**
**- Ultrasound Imaging**
**Treatment Planning Software, Treatment Delivery Hardware and Immobilization and Positioning Hard- and Software for**
**- Radiosurgery**
**- Radiotherapy**

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.:** 713160975

**Valid from:** 2020-01-01
**Valid until:** 2024-05-26

Digitally signed by Botnaru Andrei
Date: 2021.12.15 10:40:01 EET
Reason: MoldSign Signature
Location: Moldova

**Date,** 2019-11-11

Christoph Dicks
Head of Certification/Notified Body


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

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

TÜV®