



## **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

Date.

2019-11-11

Christoph Dicks

Head of Certification/Notified Body

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