



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 078360 0026 Rev. 00

Manufacturer:

LAP GmbH Laser Applikationen

Zeppelinstr. 23
21337 Lüneburg
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 078360 0026 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10_078360_0026_Rev.00)

Report No.: 713178258

Valid from: 2021-02-26

Valid until: 2026-02-25

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-02-26



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No. G10 078360 0026 Rev. 00

Classification:	IIb
Device Group:	Z110290 - VARIOUS NUCLEAR MEDICINE INSTRUMENTS
Intended Purpose:	The THALES 3D MR SCANNER system is designed to measure the characteristic radiation beam for an irradiation unit. The beam data are stored in the software program and can be exported from there for use during commissioning in a treatment planning system (TPS) or for quality assurance. The THALES 3D MR SCANNER system can be used with irradiation units with integrated magnetic resonance imaging and a magnetic field of less than or equal to 0.35 tesla.

The validity of this certificate depends on conditions and/or is limited to the following: - none -