

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Asclepion Laser Technologies GmbH
Brüsseler Str. 10
07747 Jena
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2015-12-03
Certificate Registration No.: SX 60105769 0001
An audit was performed. Report No.: 21232818 001
This Certificate is valid until: 2018-12-02

Certification Body



Date 2015-12-01



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60105769 0001
Report No.: 21232818 001

Organization: Asclepion Laser Technologies GmbH
Brüsseler Str. 10
07747 Jena
Deutschland

Scope: Design and development, production, installation and servicing of surgical and dermatological lasers, electrotherapeutical medical devices, local skin cooling systems, sterile and re-sterilisable laser fibers, percutaneous sheaths for the area of ENT, GYN, urology, dermatology, plastic and endovascular surgery, laser supply systems, and light fibers

Certification Body



Date: 2015-12-01



Dipl.-Ing. D. Meier