Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021

Registration No.: SX 1217245-1

Certificate Holder: Dr. Mach GmbH & Co. KG

Am Brucker Feld 4

85567 Grafing b. München

Germany

Scope: Design and development, production, distribution, installation

and service of operating lights, examination lights and video

systems.

Contract manufacture for mechanical components.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

 Report No.:
 1185215-100

 Effective date:
 2025-06-20

 Expiry date:
 2028-06-19

 Issue date:
 2025-06-11

Replaces certificate SX 1217245-1 issued 2025-02-18

Dipl.-Ing. (FH) Martin Wolf TÜV Rheinland LGA Products GmbH

Tillystraße 2 · 90431 Nürnberg · Germany

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This certificate can be validated on https://www.certipedia.com





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The scope of certification also covers the following sites:

installation and service of
ems.
mination lights and video

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