

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.: 1165405-100
Effective date: 2025-02-18
Expiry date: 2025-06-19
Issue date: 2025-02-18
Replaces certificate SX 1217245-1 issued 2025-02-05

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


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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Dr. Mach GmbH & Co. KG Am Brucker Feld 4 85567 Grafing b. München Germany	Design and development, production, distribution, installation and service of operating lights, examination lights and video systems. Contract manufacture for mechanical components.
/02	c/o Dr. Mach GmbH & Co. KG Großostheimer Str. 33B 63868 Großwallstadt Germany	Production and distribution of operating lights, examination lights and video systems.

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