

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2233460-1

Certificate Holder: Spectralytics Inc.
125 3rd Street South
Dassel MN 55325
USA

Scope: For the Contract Micro Machining of Medical Device
Components using Laser and Complementary Technology

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.: 234228710-11

Effective date: 2025-09-11

Expiry date: 2027-10-14

Issue date: 2025-09-11

Replaces certificate SX 2233460-1 issued 2024-09-19.

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	Spectralytics Inc. 125 3rd Street South Dassel MN 55325 USA	Activities related to Manufacturing
/02	Spectralytics Inc. 145 3rd Street South Dassel MN 55325 USA	Activities related to Manufacturing

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