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

For the Contract Micro Machining of Medical Device Scope:

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.: 234215532-11 Effective date: 2024-10-15 2027-10-14 Expiry date: Issue date: 2024-09-19

Replaces certificate SX 2233460-1 issued 2023-05-23.

Melissa Di Buono-Russo

Melissa DRusso

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

TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany





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125 3rd Street South Dassel MN 55325

USA

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	Spectralytics Inc. 125 3rd Street South Dassel MN 55325 USA	For the Contract Micro Machining of Medical Device Components using Laser and Complementary Technology
/02	Spectralytics Inc. 145 3rd Street South Dassel MN 55325 USA	For the Contract Micro Machining of Medical Device Components using Laser and Complementary Technology
/03	Spectralytics Inc.	For the Contract Micro Machining of Medical Device Components using
	8701 95th Avenue North	Laser and Complementary Technology
	Brooklyn Park MN 55445	
	USA	

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



