

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2422109-1

Certificate Holder: NextPhase Medical Devices LLC
110 Forbes Boulevard
Mansfield MA 02048
USA

Scope: Design and Development, Contract Design and Development, Servicing, and Maintenance for Medical Devices and Active Implantable Medical Devices. Contract Manufacturing and Servicing of general active, active implantable, and non-active medical devices, packaging, moist heat sterilization, and distribution of both sterile and nonsterile products.

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.: 234227907-11

Effective date: 2025-09-02

Expiry date: 2026-08-28

Issue date: 2025-09-02

Replaces certificate SX 2422109-1 issued 2024-01-17



Melissa Di Buono-Russo
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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