Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2422109-1

Certificate Holder: NextPhase Medical Devices LLC

110 Forbes Boulevard Mansfield MA 02048

USA

Scope: Subcontracted Design and Development, Servicing,

maintenance for Medical Devices, Active Implantable Medical

Devices and In Vitro Diagnostics Medical Devices.

Subcontracted Manufacturing and servicing of general active, active implantable and non-active medical devices, packaging, moist heat and ethylene oxide gas 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.:
 234204707-11

 Effective date:
 2024-01-17

 Expiry date:
 2026-08-28

 Issue date:
 2024-01-17

Replaces certificate SX 2422109-1 issued on 2022-07-29

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

Dipl.-Ing. S. Pane TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany



