

NSAI

Certificate of Registration of Quality Management System to ISO 13485:2016

The National Standards Authority of Ireland certifies that:
NextPhase Medical Devices, LLC
88 Airport Drive,
ROCHESTER, NH, 03867
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

Design, Manufacture, Contract Manufacturing, Assembly, Packaging, Warehousing and Distribution of Disposable Medical Devices.

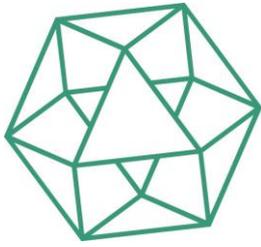
Additional sites covered under this multi-site certification are listed on the Annex (File No. CM19.8796)

Approved by:
Pamela Burdette Miller
Certification Manager

Registration Number: CM19.8796
Certification Granted: December 09, 2025
Effective Date: December 09, 2025
Expiry Date: July 11, 2027



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Annex to Certificate Number: CM19.8796

Scope of Registration:

Design, Manufacture, Contract Manufacturing, Assembly, Packaging, Warehousing and Distribution of Disposable Medical Devices.

Activity

Location

Design, Manufacture, Assembly, Inspection, Warehousing and Distribution. Contract Manufacturing.

NextPhase Medical Devices, LLC
88 Airport Drive
Rochester, NH, 03867
USA
File No.: CM19.8796

Cleanroom Assembly, Testing, Packaging, and Inspection

NextPhase Medical Devices, LLC
Blvd. Tomas Alva Edison No 14181
Parque Industrial Tomas Alva
Edison CP 22163, Baja California
Mexico
File No.: CM19.8796/A

**Verified by:
Certification Manager**