



NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Associates of Cape Cod, Inc.
124 Bernard E. Saint Jean Drive
East Falmouth, MA 02536-4445
USA

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

The Design, Manufacture and Distribution of Limulus Amebocyte Lysate (LAL) Reagents (including In-Vitro Diagnostic Medical Devices for the Analysis of (1-->3)- β -D-Glucan to Support the Diagnosis of Invasive Fungal Disease) and Related Materials and Equipment; Contract Testing for Endotoxin and Glucan.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.3017)

Approved by:
Kevin Mullaney
Director of Certification

Registration Number: MD19.3017
Certification Granted: December 22, 2006
Effective Date: April 09, 2024
Expiry Date: December 21, 2024





Annex to Certificate Number: MD19.3017

Scope of Registration:

The Design, Manufacture and Distribution of Limulus Amebocyte Lysate (LAL) Reagents (including In-Vitro Diagnostic Medical Devices for the Analysis of (1-->3)- β -D-Glucan to Support the Diagnosis of Invasive Fungal Disease) and Related Materials and Equipment; Contract Testing for Endotoxin and Glucan.

Activity

Location

Headquarters, Manufacturing,
Design & Development, Testing,
Distribution, Sales & Marketing

Associates of Cape Cod, Inc.
124 Bernard E. Saint Jean Drive
East Falmouth, MA 02536-4445
USA
File No.: MD19.3017

Warehouse

Associates of Cape Cod, Inc.
116 Bernard E. St. Jean Drive
East Falmouth, MA 02536-4445
USA
File No.: MD19.3017/A

Administration, Customer Service

Associates of Cape Cod, Inc.
81 Technology Park Drive
East Falmouth, MA 02536-4445
USA
File No.: CM19.3017/C

Verified by:
Director of Certification