



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 Reagents and Related Materials and Software for the Detection of Endotoxin and Glucan and Distribution of Related Detection Equipment. Design, Manufacture and Distribution of 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 Software and the Distribution of Related Analysis 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: January 03, 2025
Expiry Date: December 21, 2027





Annex to Certificate Number: MD19.3017

Scope of Registration:

The Design, Manufacture and Distribution of Reagents and Related Materials and Software for the Detection of Endotoxin and Glucan and Distribution of Related Detection Equipment. Design, Manufacture and Distribution of 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 Software and the Distribution of Related Analysis 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

Receiving, Incoming Inspection,
Warehousing, Shipping

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,
Technical Service, Installation,
Servicing

Associates of Cape Cod, Inc.
81 Technology Park Drive
East Falmouth, MA 02536-4445
USA
File No.: MD19.3017/C

**Verified by:
Director of Certification**