

NSAI

Certificate of Registration of Quality Management System to 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. CM19.3017)

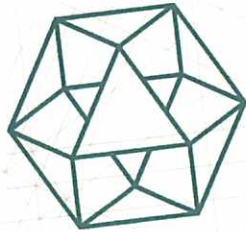
Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices
/ Head of Notified Body

Registration Number: CM19.3017
Certification Granted: December 18, 2018
Effective Date: December 22, 2018
Expiry Date: December 21, 2021



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800
National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412



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Annex to Certificate Number: CM19.3017

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.: CM19.3017

Warehouse

Associates of Cape Cod, Inc.
116 Bernard E. St. Jean Drive
East Falmouth, MA 02536-4445
USA
File No.: CM19.3017/A

**Verified by:
Operations Manager**