

# 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)- $\beta$ -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:  
Kevin Mullaney  
Director of Certification

---

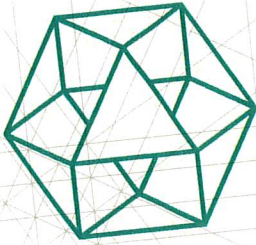
Registration Number: CM19.3017  
Certification Granted: December 18, 2018  
Effective Date: December 22, 2022  
Expiry Date: December 21, 2024



---

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





# NSAI

## **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)- $\beta$ -D-Glucan to Support the Diagnosis of Invasive Fungal Disease) and Related Materials and Equipment; Contract Testing for Endotoxin and Glucan.**

### **Activity**

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

Warehouse

### **Location**

Associates of Cape Cod, Inc.  
124 Bernard E. Saint Jean Drive  
East Falmouth, MA 02536-4445  
USA  
File No.: CM19.3017

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

**Verified by:  
Director of Certification**