

Declaration of Conformity

In vitro Diagnostic Medical Devices:

**Fungitell[®], Assay for (1→3)-β-D-Glucan in Serum
Fungitell STAT[®], Assay for (1→3)-β-D-Glucan in Serum and
BG Analytics[®], β -Glucan Analysis Software**

This is to certify that Fungitell[®] (Catalog number FT001), Fungitell STAT[®] (Catalog number FT007) and BG Analytics[®] (BGA007) conform to the applicable requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

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

Authorized Representative: Emergo Europe,
Prinsessegracht 20,
2514 AP, The Hague,
The Netherlands

Classification: Self-certified IVD

Conformity Assessment Route: Annex III.



AJ Meuse
AJ Meuse, Ph.D.
CEO, Associates of Cape Cod, Inc

FALMOUTH, MA, USA
Place

17 MAY 2022
Date