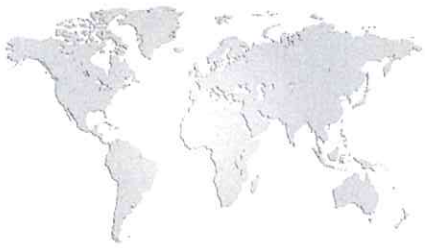
EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

InspireMD Ltd.

4 Menorat Hamaor St., 6744832 Tel Aviv, Israel

Certified location:

4 Menorat Hamaor St., 6744832 Tel Aviv, Israel

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 51168-Z4-00, the decision dated 2019-12-02 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-12-02 to 2024-05-26

Registration No.: 51168-16-05

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-12-02
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Digitally signed by Ostapciuc Alexandr
Date: 2021.12.20 16:01:15 EET
Reason: MoldSign Signature
Location: Moldova

Annex to the EC Certificate No. 51168-16-05

Valid from 2019-12-02 to 2024-05-26

Revision status of the annex: 0 dated 2019-12-02

Devices/device categories included in the certificate:

Class III:

- MGuard Prime Coronary Stent System – Embolic Protective stent
- CGuard Carotid Embolic Prevention Stent System

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

DEKRA Certification GmbH • DEKRA • Stuttgart, Handwerkstraße 15 • D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-12-02
Notified Body ID-number: 0124