EC Design Examination Certificate

according the directive 93/42/EEC, Annex II (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies for the manufacturer

InspireMD Ltd.

4 Menorat Hamaor St., 6744832 Tel Aviv, Israel

that the design dossier for the product(s) described in the annex complies with the requirements of the directive 93/42/EEC. This certificate is based on the result of the examination of the design dossier according to the directive 93/42/EEC Annex II.4 as documented in the report mentioned in the annex.

Product: MGuard Prime Coronary Stent System
Embolic Protection stent

This certificate is valid from 2017-11-13 to 2022-11-12

Registration No.: 51168-23-B5

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-11-03
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

Annex to the EC Design Examination Certificate No. 51168-23-B5

Revision status: 0

valid from 2017-11-13 to 2022-11-12

Report number: 51168-P2-04

Product: MGuard Prime Coronary Stent System Embolic Protection stent

Intended use:

MGuard Prime Coronary Stent System is indicated for improving luminal diameter in vessels with reference diameter from 2.5 to 4.0 mm having lesion length <38 mm and providing embolic protection.

Technical data:

Balloon Length (mm)	9 / 14 / 19 / 24 / 30 / 34 / 38		
Stent Length (mm)	8 / 13 / 18 / 23 / 28 / 33 / 38		
Balloon Diameter (mm)	2.5 / 2.75 / 3.0 / 3.25 / 3.5 / 4.0		
Article Numbers	MGP2508 MGP2513 MGP2518 MGP2523 MGP2528 MGP2533 MGP2538	MGP2708 MGP2713 MGP2718 MGP2723 MGP2728 MGP2733 MGP2738	MGP3008 MGP3013 MGP3018 MGP3023 MGP3028 MGP3033 MGP3038
	MGP3208 MGP3213 MGP3218 MGP3223 MGP3228 MGP3233 MGP3238	MGP3508 MGP3513 MGP3518 MGP3523 MGP3528 MGP3533 MGP3538	MGP4008 MGP4013 MGP4018 MGP4023 MGP4028 MGP4033 MGP4038

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