

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



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
ZLG-BS-295.10.02
www.zlg.de

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	MGP2708	MGP3008
	MGP2513	MGP2713	MGP3013
	MGP2518	MGP2718	MGP3018
	MGP2523	MGP2723	MGP3023
	MGP2528	MGP2728	MGP3028
	MGP2533	MGP2733	MGP3033
	MGP2538	MGP2738	MGP3038
	MGP3208	MGP3508	MGP4008
	MGP3213	MGP3513	MGP4013
	MGP3218	MGP3518	MGP4018
	MGP3223	MGP3523	MGP4023
	MGP3228	MGP3528	MGP4028
	MGP3233	MGP3533	MGP4033
	MGP3238	MGP3538	MGP4038



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