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., Israel 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: CGuard Carotid Embolic Prevention Stent System

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

Registration No.: 51168-23-C3

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

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-11-08
Notified Body ID-Number: 0124

Digitally signed by Ostapciuc Alexandr
Date: 2021.12.20 16:01:10 EET
Reason: MoldSign Signature
Location: Moldova

Annex to the EC Design Examination Certificate No. 51168-23-C3

Revision status: 0

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

Report number: 51168-P3-01

Product: CGuard Carotid Embolic Prevention Stent System

Intended use:

The CGuard Carotid Stent System is indicated for improving carotid luminal diameter in patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization

Technical data:

Article No. Rapid Exchange	Stent Diameter [mm]	Stent Length [mm]
CRX0620	6.0	20
CRX0630	6.0	30
CRX0640	6.0	40
CRX0660	6.0	60
CRX0720	7.0	20
CRX0730	7.0	30
CRX0740	7.0	40
CRX0760	7.0	60
CRX0820	8.0	20
CRX0830	8.0	30
CRX0840	8.0	40
CRX0860	8.0	60
CRX0920	9.0	20
CRX0930	9.0	30
CRX0940	9.0	40
CRX0960	9.0	60
CRX1020	10.0	20
CRX1030	10.0	30
CRX1040	10.0	40
CRX1060	10.0	60

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