Federal Agency for Medicines and Health Products (FAMHP)
Avenue Galilée 5/03
1210 BRUSSELS
www.afmps.be

Directorate-General Post-Authorization (DG POST) /Health Products Division
/ Medical Devices Unit

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InspireMD Ltd.
Menorat Hamaor Street 4
6744832 Tel Aviv
Israel
tamarn@inspiremd.com

Your letter dated	Your references	Our references	Appendices	Date
	-	2022/96/1312248	2	See signature

Re: 2022/96/1312248 – Art. 97 "Other non-compliance" of Regulation 2017/745 relating to medical devices

Dear Sir/Madam,

This document concerns the **CGuard Carotid Stent System** manufactured by **InspireMD Ltd.** (located at Menorat Hamaor Street 4; 6744832 Tel Aviv; Israel), covered until 12 November 2022 by the certificates described in Appendix 1 issued by the DEKRA notified body and whose authorized representative is Obélis S.A. Boulevard Général Wahis, 53 ; 1030 Brussels; Belgium

In view of Articles 94 and 97 of (EU) Regulation 2017/745 of the European Parliament and Council of 05 April 2017 relating to medical devices, amending Directive 2001/83/CE, (EC) Regulation no. 178/2002 and (EC) Regulation no. 1223/2009 and repealing Council Directives 90/385/CEE and 93/42/CEE, (hereafter referred to as: "Regulation 2017/745");

In view of Article 79 of the Law of 22 December 2020 relating to medical devices;

In view of your initial derogation request of 18 October 2022;

In view of your emails dated 25 August 2022; 17 October 2022; 16 November 2022; 22 December 2022; 19 January 2023; 27 January 2023 and 01 February 2023 in response to our questions;

In view of the following documents received:

- EC certificate
- Completed derogation form
- Labelling
- IFU
- Alternatives
- DoC
- Mandate to Obelis
- EC Certificate
- DoC
- Letter from Dekra
- Letter from Dekra for the next audit
- Product description and clinical benefits

The conclusions of the evaluation performed pursuant to Article 94 of regulation 2017/745 are the following:

- The evaluation confirms the non-compliance of the devices since 12 November 2022 following expiration of CE certificate 51168-23-C3.
- According to the evaluation, the devices did not present an unacceptable risk to patient health or safety insofar as:
    - The benefit-risk ratio remains positive.
    - The analysis of vigilance data identifies no public health hazard.

Given that:

- Until 12 November 2022, the device was certified under Directive 93/42/EEC.
- The certificate was not withdrawn or limited for safety reasons.
- The company, InspireMd, submitted a certification request to the DEKRA notified body.
- The certification procedure under regulation 2017/745 was initiated with a notified body.
- We received an attestation from the manufacturer that the devices are in compliance with Regulation 2017/745.
- Article 97, paragraph 1 of regulation 2017/745 indicates: *"Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance."*
- The document: *MDCG Position Paper 2022-18 – MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of an MDR certificate* was published on 09 December 2022.

As a result, pursuant to Article 97 paragraph 1 of Regulation 2017/745, the Federal Agency for Medicines and Health Products (FAMHP) does not object to the continuation, under conditions, of the marketing in Belgium of the CGuard Carotid Stent System pending compliance, which should take place by 15 August 2023 at the latest.

The conditions for continuation of marketing are the following:

1. No incident or risk of serious material vigilance incident jeopardizing the benefit-risk balance of this medical device established in the clinical evaluation report for these devices;
2. The obligation to inform your clients of the situation corresponding to this compliance period.
3. The manufacturer and its authorized representative (if applicable) must ensure that the devices supplied within the context of this derogation are entirely and without exception compliant with the requirements stipulated when the corresponding CE certificates were valid. However, with regard to post-marketing surveillance, marketing surveillance, vigilance and registration of economic operators and devices, the requirements of MDR regulation

2017/745 / IVDR 2017/746 apply instead of the corresponding requirements in Directives 93/42/CEE – 90/385/CEE – 98/79/CE.

The FAMHP reserves the right to inspect your premises and to monitor this device in institutions where it is available. In the event of findings of non-compliance which may result in a risk of compromising public health and/or the safety of patients, users or, if applicable, other persons, the Minister or his/her delegate may take measures.

The manufacturer or its agent must inform the FAMHP within a period of 5 working days from receipt of information of progress made with the notified body via the email address derogation.meddev@afmps.be: step-by-step update of the plan, audit reports, Corrective and Preventive Action (CAPA) plans, CE certificate, etc. Moreover, please keep the FAMHP updated on any information deemed relevant within the context of this derogation (via the email address derogation.meddev@afmps.be).

The relevant economic operators are also asked to comply with the post-marketing surveillance of these devices, which includes but is not limited to keeping the FAMHP updated on any vigilance case, monitoring the performance of the device and reporting to the FAMHP any corrective actions in the field (via the email address vigilance.meddev@afmps.be). If any incidents or corrective actions need to be reported to the FAMHP, the references of this letter must be clearly mentioned.

In case of a disagreement with the previous conditions, you have 15 calendar days from receipt of this letter to express your observations that will be submitted for evaluation by the FAMHP during a maximum period of 45 calendar days in order to definitively adopt the necessary measures. Please send these by email toderogation.meddev@afmps.be with the following subject line “appeal 2022/99”. After this evaluation, you will be notified of a final decision.

At that time, if you do not agree with this decision, you may make an appeal to the Council of State, pursuant to Article 19 of the coordinated laws on the Council of State, without this appeal suspending this decision. The appeal must be made with a period of 60 days following receipt of this decision, in the form of a written request, signed by you or a lawyer, or it will be inadmissible. This request must be sent by registered mail to the First President of the Council of State, rue de la Science 33, 1040 Brussels, or using the electronic procedure. For more information, please refer to the above-mentioned laws, the Regent’s Order of 23 August 1948 determining the procedure for administrative appeal to the Council of State as well as the website of the Council of State: www.conseil-etat.be.

For more information on this file, you may contact the FAMHP (email: derogation.meddev@afmps.be).

Sincerely,

Xavier De Cuyper (Signature)

Digitally signed by Xavier De Cuyper (Signature)
DN: c=BE, cn=Xavier De Cuyper (Signature), sn=De Cuyper, givenName=Xavier Bernard, serialNumber=57020339349
Date: 14 February 2023 18:04:35 +01'00'

Xavier De Cuyper General

Administrator

Appendices:

- Appendix 1: CE Certificate 51168-23-C3
- Appendix 2: CE Certificate 51168-16-05

Appendix 1: CE Certificate 51168-23-C3

DEKRA

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 * Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart: 2017-11-08
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

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

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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

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

Appendix 2: CE Certificate 51168-16-05

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

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; 2019-12-02
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

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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.

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