

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** CE 596357  
Issued To: **Neuravi Limited**  
**Block 3**  
**Ballybrit Business Park**  
**Galway**  
**Ireland**

In respect of:

**EmboTrap Revascularization System**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2013-10-03**

Date: **2020-05-27**

Expiry Date: **2023-10-02**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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### EmboTrap Revascularization System

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
ET-007	EMBOTRAP	5mm x 21mm	The EmboTrap® Revascularization Device (the Device) is intended to be used to restore blood flow in patients experiencing an acute ischemic stroke due to a large vessel neurovascular occlusion. The Device is designed for use in the anterior and posterior neurovasculature in vessels of diameter 1.5mm to 5mm, such as the internal carotid artery, the M1 and M2 segments of the middle cerebral artery, the A1 and A2 segments of the anterior cerebral artery, the basilar, the posterior cerebral and the vertebral arteries.	Class III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
ET-007-521	EMBOTRAP II	5mm x 21mm	EmboTrap™ II Revascularization Device (the Device) is intended to be used to restore blood flow in patients experiencing an acute ischemic stroke due to a large vessel neurovascular occlusion. The Device is designed for use in the anterior and posterior neurovasculature in vessels of diameter 1.5mm to 5mm, such as the internal carotid artery, the M1 and M2 segments of the middle cerebral artery, the A1 and A2 segments of the anterior cerebral artery, the basilar, the posterior cerebral and the vertebral arteries.	Class III
ET-007-533	EMBOTRAP II	5mm x 33mm		Class III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
ET307522	EMBOTRAP III	5mm x 22mm	The EMBOTRAP™ III Revascularization Device (the Device) is intended to be used to restore blood flow in patients experiencing an acute ischemic stroke due to a large vessel neurovascular occlusion. The Device is designed for use in the anterior and posterior neurovasculature in vessels, such as the internal carotid artery, the M1 and M2 segments of the middle cerebral artery, the A1 and A2 segments of the anterior cerebral artery, the basilar, the posterior cerebral and the vertebral arteries.	Class III
ET307537	EMBOTRAP III	5mm x 37mm		Class III
ET307645	EMBOTRAP III	6.5mm x 45mm		Class III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GCE4528	CERENOVUS NIMBUS	4.5mm x 28mm	The CERENOVUS NIMBUS Device (the Device) is intended to be used to restore blood flow in patients experiencing an acute ischemic stroke due to a large vessel neurovascular occlusion. The Device is designed for use in the anterior and posterior neurovasculature in vessels of diameter 1.5 mm to 5.0 mm, such as the internal carotid artery, the M1 and M2 segments of the middle cerebral artery, the A1 and A2 segments of the anterior cerebral artery, the basilar, the posterior cerebral and the vertebral arteries.	Class III

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## Certificate History

Date	Reference Number	Action
03 October 2013	10140525	First Issue.
23 February 2016	10161054	Change in Legal Manufacturer Address following relocation of Head Office.
06 May 2016	10161991	Shelf life extension of EmboTrap product to 3 years.
05 July 2016	10163200	DuPont Tyvek packaging change and the addition of the EmboTrap II products to the range.
29 May 2018	8924656	Supplement review covering the UV bond process change and update to the in-process colour acceptance criteria.
04 June 2018	8918628	Introduction of a variable ETO sterilisation load (1-3 pallets) for Embotrap Devices.
20 August 2018	8939388	Certificate Renewal.
13 November 2018	9641867	Addition of the Geometric Clot Extractor (GCE) to the product range.
27 February 2019	8154450	Traceable to NB 0086.

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## Certificate History

Date	Reference Number	Action
Current	3043227	Addition of product codes ET307522, ET307537, and ET307645. Product name change from "Geometric Clot Extractor" to "CERENOVUS NIMBUS". Addition of products table in supplementary information section.

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**Supplementary Information to CE 596357 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3**

Issued to: **Neuravi Limited**  
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**Date:** 03 September 2021

**Changes Approved:**

Date	Reference Number	Action
03 September 2021	3477381	Approval of a single bioburden monitoring strategy and endotoxin sampling plan and a low density load configuration for sterilization (for EmboTrap II, EmboTrap III, and Cerenovus Nimbus models).

03 September 2021

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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

<b>Certificate</b>	<b>Directive and Annex</b>	<b>Reference Number</b>	<b>Changes approved</b>
CE 596357	93/42/EEC Annex II Section 4	3477381	Approval of a single bioburden monitoring strategy and endotoxin sampling plan and a low density load configuration for sterilization (for EmboTrap II, EmboTrap III, and Cerenovus Nimbus models).

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Gary Slack  
Senior Vice President, Medical Devices