Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 3 din 13.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albişoara 16/1 of.7, or. Chişinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- CERENOVUS NIMBUS: GCE4528

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Digitally signed by Poiata Vitalie
Date: 2023.10.13 17:09:44 EEST
Reason: MoldSign Signature
Location: Moldova

Data 13.10.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Kojevnikov Dmitrii
Date: 2023.10.13 17:10:53 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- CERENOVUS NIMBUS: GCE4528

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 13.10.2023

LifeTech Consulting s.r.l.
Str. Vulturilor nr. 56-58, Sector 3, București
RO26420806 - J40/603/2010
ING Bank Sucursala Bucuresti
RO24INGB0000999901828832
tel/fax: 021 323 3016 - mobil: 0721 285085
email: office@life-tech.ro

To: Whomever it may concern

Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

26.10.2022

MANUFACTURERS AUTHORIZATION

We, **Lifetech Consulting S.R.L.**, authorized distributor of **Neuravi Limited a Johnson & Johnson company**, manufacturer of medical products with principal place of business at Block 3, Ballybrit Business Park, Galway, Irlanda, hereby confirm that **Biosistem mld SRL** with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, is authorized by the company **Lifetech Consulting S.R.L.**, to carry out the registration of products manufactured by **Neuravi Limited a Johnson & Johnson company** in Republic of Moldova.

This authorization is valid for 1 year from the date of issuance and automatically renewable if no termination letter issued.

Bogdănel Scripcă

Legal representative

Lifetech Consulting S.R.L.

Legal Manufacturer Name:	Neuravi Limited
Address:	Neuravi Limited Block 3, Ballybrit Business Park Galway, Ireland

Product Name	EmboTrap
Product Classification	III
Classification Rule	Rule 6
Conformity Pathway	Annex II
Name and ID of notified body	BSI 2797
CE Certificate Number	CE 596356 – Full Quality Assurance
Design Certificate Number	CE 596357

Neuravi declares the above documented product(s) issued under the responsibility of the manufacturer meets the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC.
This declaration authorizes Neuravi to affix the CE-marking to the products listed herein.

Niall Fox

Digitally signed by Niall Fox
DN: cn=Niall Fox, o=Cerenovus, ou, email=nfox5@its.jnj.com, c=IE
Reason: I am approving this document.
Date: 2020.06.17 18:01:22 +01'00'
Adobe Reader version: 11.0.10

17-June-2020

Date of Approval

Niall Fox
Associate Director Regulatory Affairs

Location of Approval: Galway, Ireland

CE Mark Implementation Details

Neuravi Revascularization Devices	Product Name	Product Code*	Date CE Mark Affixed (Date it is added to labels and used on product)
	EmboTrap	ET-007	Immediate, 15th October 2013
	EmboTrap II	ET-007-533 ET-007-521	Immediate, 14th July 2016
	CERENOVUS NIMBUS	GCE4528	Immediate, 13th November 2018
	EMBOTRAP III	ET307522 ET307537 ET307645	Immediate, 27th May 2020

Approvals		
Print Name & Role	**Signature**	**Date**
Niall Fox *Associate Director Regulatory Affairs*	Niall Fox Digitally signed by Niall Fox DN: cn=Niall Fox, o=Cerenovus, ou, email=nfox5@its.jnj.com, c=IE Reason: I am approving this document Date: 2020.06.17 17:59:31 +01'00' Adobe Reader version: 11.0.10	17-June-2020

*The product code represents the device identifier component of the unique device identifier (UDI). The production identifier(s) used in the UDI will vary with each production lot (e.g. lot number).

Declaration Revision History:

DCN #	Revision #	Brief description Changes
152	01	Initial issue of DOC for EmboTrap
377	02	Update of the DOC to correct typographical error in the part number
429	03	Update of the DOC to include the new address for the legal manufacturer
489	04	Update to the DOC to include the new EmboTrap II product codes
1046	05	Update to the DOC to align with updates to the template RA001.F02
1179	06	Update to the DOC to include the new EmboTrap GCE product codes
1285	07	Update to the DOC to reference new notified body number for BSI Netherlands

1787	08	Update to include the new EMBOTRAP III product codes and update to include product name change from Geometric Clot Extractor (GCE) to CERENOVUS NIMBUS.

Gareth Clarke

Digitally signed by Gareth Clarke
DN: c=US, o=JNJ, ou=Subscribers, cn=Gareth Clarke, 0.9.2342.19200300.100.1.1=1528 10030
Reason: I am certifying this document
Date: 2020.06.17 17:56:33 +01'00'
Adobe Acrobat version: 11.0.10

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 596356**

Issued To: **Neuravi Limited**
Block 3
Ballybrit Business Park
Galway
Ireland

In respect of:

The design and manufacture of sterile revascularisation devices for the treatment of stroke.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II 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: **2020-06-01** Expiry Date: **2023-10-02**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 596356

Issued To:

Neuravi Limited
Block 3
Ballybrit Business Park
Galway
Ireland

Number	Device Name	Intended Purpose per IFU
Class III		
---	EMBOTRAP	See CE 596357
---	EMBOTRAP II	See CE 596357
---	EMBOTRAP III	See CE 596357
---	CERENOVUS NIMBUS	See CE 596357

First Issued: **2013-10-03** Date: **2020-06-01** Expiry Date: **2023-10-02**

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 596356**
Date:	**2020-06-01**
Issued To:	**Neuravi Limited** **Block 3** **Ballybrit Business Park** **Galway** **Ireland**

Subcontractor:	**Service(s) supplied**
ADMEDES GmbH Rastatter Str. 15 75179 Pforzheim Germany	**Crucial Supplier**
Advant Medical Limited Parkmore Business Park West Galway Ireland	**Manufacture** **Packaging**
Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Co. Offaly Ireland	**ETO Sterilization**

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By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 596356**
Date: **2020-06-01**
Issued To: **Neuravi Limited**
Block 3
Ballybrit Business Park
Galway
Ireland

Date	Reference Number	Action
03 October 2013	7958838	First Issue.
23 February 2016	8468600	Change in Legal Manufacturer Address following relocation of Head Office.
02 November 2016	8632262	Addition of crucial supplier Admedes Scheuessler GmbH, Rastatter Str. 15, 75179 Pforzheim, Germany.
20 August 2018	8939387	Certificate Renewal.
27 February 2019	8154450	Traceable to NB 0086.
Current	3201596	Change of subcontractor name from "Admedes Scheuessler GmbH" to "Admedes GmbH" and from "Synergy Health Ireland Ltd (Synergy Health – AST – Ireland)" to "Synergy Health Ireland Ltd". Addition of product table in supplementary information section.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Neuravi Limited
Block 3
Ballybrit Business Park
Galway
Ireland

Holds Certificate Number: **MD 593929**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development and manufacture of sterile revascularisation devices for the treatment of stroke.

Previous certificate expired June 2, 2019
Recertification audit ended May 13, 2019

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2013-06-03
Latest Revision Date: 2019-07-31

Effective Date: 2019-07-31
Expiry Date: 2022-06-02

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UKAS MANAGEMENT SYSTEMS 003