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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 5 din 13.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău
(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:

- NeVa Mechanical Thrombectomy System

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 17:09:51 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 17:11:04 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:

- NeVa Mechanical Thrombectomy System

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 13.10.2023

LETTER OF AUTHORIZATION

October 12, 2023

To Whom It May Concern

We**, Vesalio, LLC**, a company with its registered address at West End Ave, Suite 500 3200, TN 37203 Nashville, United States ("**Vesalio**"), are party to a certain exclusive distribution agreement with **Eximia Medical S.r.l.,** a company with its registered address at Bucureşti Sectorul 2, Strada GHEORGHE ŢIŢEICA, Nr. 142, BIROU 8, Etaj 4, Romania ("**Distributor**"), whereby Distributor has a right to distribute and shall obtain and maintain all registrations, permits, licenses and approval necessary or appropriate for the importation and sales of the products in the territory of Romania and Republic of Moldova.

If there are any inquiries regarding this matter, please contact William von Brendel - VP, International Business, e-mail: wvb@vesalio.com.

For and on behalf of Vesalio

William von Brendel

VP, International Business

VESALIO LLC LIMITED LIABILITY COMPANY TENNESSEE 2013

615-206-7788
info@vesalio.com
3200 West End Ave, Ste 500
Nashville, TN 37203

Nr. 2909/13.10.2023

To: Whom it may concern

Ref. Biosistem Mld SRL
Str. Albisoara Nr. 16/1 ap.7
Chisinau, R. Moldova

DISTRIBUTOR AUTHORIZATION

We, Eximia Medical S.R.L, a Romanian company, with its registered office address at Bucureşti, Sector 2, Strada GHEORGHE ŢIŢEICA, Nr. 142, BIROU 8, Etaj 4, Romania, authorized distributor (representative) for Romania and Moldova of Vesalio, LLC, a company with its registered address at West End Ave, Suite 500 3200, TN 37203, Nashville, United States ("Vesalio"), hereby confirm that:

Biosistem Mld SRL, a Moldavian company, with business office address at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, Phone: +373 22 808517; +373 22 808719; Fax. +373 22 808519, e-mail: biosistem.mld@gmail.com, IDNO (fiscal code) 1010600028048, VAT Code 0607490, bank account MD71PR0022241908460001840 USD, opened at ProCredit Bank S.A.. Chisinau Branch, SWIFT Code: PRCBMD22, legally represented by Poiata Vitalie as Administrator,

is authorized by us, to carry out the registration of products manufactured by Vesalio, LLC, in the records of the Ministry of Health of Republic of Moldova.

This authorization is valid from the date of its release until 31.12.2023.

EXIMIA MEDICAL S.R.L.
by Manager Ungureanu Mihaela

Eximia Medical SRL
Titeica Office Building - 142 Gheorghe Titeica Street, 3rd floor, 020304, District 2,
Bucharest, Romania Tel.: +4031 426 03 92 Fax: +4031 426 03 93
office@eximiamedical.ro www.eximiamedical.ro

DECLARATION OF CONFORMITY

Manufacturer: **Vesalio LLC.**
Address: 105 N. Pointe Drive
Lake Forest, CA – 92630
United States of America
SRN: US-MF-000016994

Product: NeVa Mechanical Thrombectomy System
Basic UDI-DI: 0851279008NEVA2J

Model	Product Description	UDI-DI (GTIN)
30040V-T	NeVa T	00851279008002
30041V-TL	NeVa Tx	00851279008040
30010V-M1	NeVa M1	00851279008019
30011V-M1L	NeVa M1x	00851279008057
30020V-MS	NeVa M1-S	00851279008026
30021V-MSL	NeVa M1-Sx	00851279008064
30050V-VS	NeVa VS	00851279008033
30051V-VSL	NeVa VSx	00851279008071
VN-4546-F3RR	NeVa T-3	00851279008262
VN-4546-F3RX	NeVa T-3x	00851279008279
VN-4030-03RR	NeVa 4.0 x 30 mm	00851279008798
VN-4038-F3RR	NeVa M1-3	00851279008170
VN-4038-F3RX	NeVa M1-3x	00851279008187
VN-4544-05RR	NeVa T-5	00851279008293
VN-4529-03RR	NeVa T-3S	00851279008231
VN-4529-03RX	NeVa T-3Sx	00851279008248
VN-6035-F2RR	NeVa IC	00851279008316
VN-6044-F3RR	NeVa IC-3	00851279008330
VN-5537-03RR	NeVa 5.5 x 37 mm	00851279008750
VN-6044-F3NR	NeVa IC-3 Net	00851279008347
VN-6035-F2NR	NeVa IC Net	00851279008323
VN-5537-03NR	NeVa 5.5 x 37 mm Net	00851279008774
VN-4546-F3NR	NeVa T-3 Net	00851279008286
VN-4537-F2NR	NeVa T Net	00851279008224
VN-4544-05NR	NeVa T-5 Net	00851279008309
VN-4038-F3NR	NeVa M1-3 Net	00851279008194
VN-4030-03NR	NeVa 4.0 x 30 mm Net	00851279008781
VN-4030-F2NR	NeVa M1 Net	00851279008163
VN-4529-03NR	NeVa T-3S Net	00851279008255
VN-4022-02NR	NeVa M1-S Net	00851279008132
EV-4030-F2RR	enVast 4.0 x 30 mm	00851279008699
EV-4038-F3RR	enVast 4.0 x 38 mm	00851279008705

EV-4537-F2RR	enVast 4.5 x 37 mm	00851279008712
EV-4546-F3RR	enVast 4.5 x 46 mm	00851279008729
EV-6035-F2RR	enVast 6.0 x 35 mm	00851279008736
EV-6044-F3RR	enVast 6.0 x 44 mm	00851279008743

Product Shelf-life: 2-year

Classification (MDD, Annex IX): Class III per Rule 7, Sub-rule 2

Intended Purpose: The NeVa Mechanical Thrombectomy System is intended to restore blood flow and remove thrombus in vessels occluded by thrombo-embolic material while experiencing an acute ischemic stroke resulting from a thrombo-embolic event and to remove clot in the coronary vasculature. The Vesalio NeVa Mechanical Thrombectomy System is positioned across the embolus or blood clot and are used to facilitate the restoration of blood flow and removal of the clot obstruction.

Two configurations are given due to marketing purposes. This means that some of the NeVa System variants are also available as enVast variants. The enVast variants have a more limited intended purpose for the coronary use only due to marketing purposes.

NeVa System variants:
The NeVa Mechanical Thrombectomy System variants are intended to restore blood flow and remove thrombus in vessels occluded by thrombo-embolic material while experiencing an acute ischemic stroke resulting from a thrombo-embolic event and to remove clot in the coronary vasculature. The Vesalio NeVa Mechanical Thrombectomy System variants are positioned across the embolus or blood clot and are used to facilitate the restoration of blood flow and removal of the clot obstruction.

enVast System variants:
The enVast Mechanical Thrombectomy System variants are intended to restore blood flow and remove thrombus in vessels occluded by thrombo-embolic material while experiencing symptoms of thrombosis in the coronary vasculature. The Vesalio enVast Mechanical Thrombectomy System variants are positioned across the embolus or blood clot and are used to facilitate the restoration of blood flow and removal of the clot obstruction.

European Representative: **MDSS GmbH**
Schiffgraben 41
30175 Hannover
Germany
SRN: DE-AR-000005430

Notified Body: **DQS Medizinprodukte GmbH**
August-Schanz-Straße 21
D-60433 Frankfurt am Main, Germany
Notified Body Number: 0297

Conformity Route: Regulation (EU) 2017/745 Annex IX

Certificates: 534720 MDR2017Q; 170780173

534720 MDR2017P; 170781867

Date CE mark was affixed: 15-SEP-2022

Expiration of DOC: 15-SEP-2027

We, Vesalio LLC, herewith declare in sole responsibility that as of the date of this declaration, the above mentioned product meets the provisions of the following regulation (EU) 2017/745 and applicable standards. All supporting documentation is retained under the premises of the manufacturer and the notified body.

Ryan Breckenridge, Management Representative	105 N. Pointe Dr. Lake Forest, CA 92630, USA Place of Issue	31-MAR-2023 Date of Issue

Revision History

Revision	Description of Change	CO#
A	Initial Release	CO #1070
B	Addition of Product shelf-life and expiration date of DOC. Update to management representative	CO #1253
C	Addition of the sub-rule for the Classification of the NeVa System	CO #1254
D	Line extension	CO #1310
E	Update expiration date for MDD certifications	CO #1312
F	Update part reference numbers	CO #1386
G	Update part reference numbers	CO #1396
H	Update Date CE mark was affixed	CO #1426
I	Update date of expiration for MDD certification and DOC	CO #1435
J	Update Date CE mark was affixed	CO #1453
K	Line extension. Update to European Representative	CO #1513
L	Update based on 5th change notification approval from Notified Body	CO #1532
L.1	Line extension. Update to Management Representative	CO #1891
M	Update per Regulation (EU) 2017:745	CO #1952
N	Add both MDR certifications references and include revision history	CO #2190

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Vesalio, LLC.

105 N. Pointe Drive
Lake Forest, CA 92630
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Mechanical Thrombectomy Devices NeVa Systems Class III

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	534720 MR2
Certificate unique ID	170746874
Effective date	2020-03-24
Expiry date	2024-05-26
Frankfurt am Main	2020-03-24

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.