ORDIN DE PLATA NR.: 170 TIP.DOC. 1

DATA EMITERII:mar?i, 12 noiembri

PLATITI: 2000-00 LEI: Doua Mii lei 00 bani

PLATITOR: (R) S.C. "OXIVIT-MED" S.R.L.
CONTUL DE PLATI/CODUL IBAN MD44ML0000000022517295O3
CODUL FISCAL :1007600044280 /

PRESTATORUL PLATITOR BC"Moldindconbank"S.A. fil."Invest" Chisinau
CODUL BANCII: :MOLDMD2X329:

BENEFICIAR (R) IMSP SPITAL UL CLINIC MUNICIPAL "SFANTA TREIME"
CONTUL DE PLATI/CODUL IBAN MD22ML0000000002251666l4
CODUL FISCAL :1003600152592 /

PRESTATORUL BENEFICIAR BC"Moldindconbank"S.A.
CODUL BANCII: :MOLDMD2X :

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-1730896670875 din 14.11.2024

TIPUL TRANSFERULUI NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:12/11/2024
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Kojevnikov Dmitrii

MIIGdAYJKoZIhvcNAQcCoIIGZTCCBmECAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBH0wggR5MIIDYaADAgECAhNHAADml2rTzDkidh/bAAAAAOaXMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIzMDMxNjE1MjYyMloXDTI2MDMxNjE1MzYyMlowgbAxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTETMBEGA1UEChMKT3hp

(semnatura electronica)

CONTABIL-SEF:Web Kojevnikov Dmitrii

MIIGdAYJKoZIhvcNAQcCoIIGZTCCBmECAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBH0wggR5MIIDYaADAgECAhNHAADml2rTzDkidh/bAAAAAOaXMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIzMDMxNjE1MjYyMloXDTI2MDMxNjE1MzYyMlowgbAxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTETMBEGA1UEChMKT3hp

L.S. (semnatura electronica)

CONDUCATOR: _____ (semnatura manuala)

CONTABIL-SEF: _____ (semnatura manuala)

SEMNATURA PRESTATORUL _____ L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Kojevnikov Dmitrii
Date: 2024.11.13 12:14:21 EET
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI AL UNITĂȚILOR DE DREPT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **1341280**

Din От **05.11.2024 13:41**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1007600044280

Denumirea
Наименование

Societatea Comercială OXIVIT-MED S.R.L.

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie
На дату выдачи данной справки задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **20.11.2024 13:41**

Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **05.11.2024 13:41**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022
Сертификат подписан электронной попдписью в соответсвие с Законом № 124 от 19.05.2022

Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceiași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлиности электронной подписи можно осуществить с помощью Государсвенной Службой Электронной Подписью (msign.gov.md)

MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

GROUPE SOCIETE GENERALE

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531861** data **19.09.2023**

Denumirea completă: **Societatea Comercială "OXIVIT-MED" S.R.L.**
Denumirea prescurtată: **S.C. "OXIVIT-MED" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1007600044280**
Data înregistrării de stat: **30.07.2007**
Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
2. Comerţul cu ridicata al parfumurilor şi produselor cosmetice
3. Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă
4. Intermedieri pentru vînzarea unui asortiment larg de mărfuri
5. Alte tipuri de comerţ cu amănuntul în magazine nespecializate
6. Alte tipuri de comerţ cu ridicata
7. Închirierea altor maşini şi echipamente

Capitalul social: **5400** lei,

Administrator: **KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociaţii:
1. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%
Beneficiar efectiv:
1.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **19.09.2023**.

Registrator în domeniul înregistrării de stat **Rusu Diana**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova

EB 0461498

Date cu caracter personal

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

EC DECLARATION OF CONFORMITY

General Applicable Directives/Standards:

EN ISO 13485 : 2016 + AC : 2016 **Quality Management System Standard** (281863 MP2016)

93/42/EEC
Conformity Assessment Route

Council Directive Concerning Medical Devices
Annex II (including section 4) 489932 MRA
Annex II (excluding Section 4) 281863 MR2

Product	Model/Reference/Catalogue Number(s)	GMDN Code	Class-Rule	Date CE Mark Affixed
Rebar™-18 Micro Catheter	105-5081-130 105-5081-153 105-5083-153	10691 Vascular Micro Catheter	Class III Rule 7	18-DEC-2003
Rebar™-27 Micro Catheter	105-5082-130 105-5082-145	10691 Vascular Micro Catheter	Class III Rule 7	

Manufacturer:
Micro Therapeutics, Inc.
DBA ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618 USA

Notified Body:
DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main, Germany
Notified Body Number: 0297

European Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the medical device directive 93/42/EEC as amended by 2007/47/EC and EN ISO 13485 : 2016 + AC : 2016. All supporting documentation is retained under the premises of the manufacturer.
Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Amnon Talmor
Sr. Regulatory Affairs Manager

Irvine, California 92618; USA
Place of Issue

11 JUN 2021
Date of Issue

This Declaration of Conformity expires on 2023-12-17.

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
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:

Implants and Instruments for Interventional Minimal Invasive Therapy according to annex.

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.	281863 MR2
Certificate unique ID	170773730
Effective date	2021-01-04
Expiry date	2024-05-26
Frankfurt am Main	2021-01-04

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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170773730
Effective date: 2021-01-04

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

Device family	Device	Class
Detachable Embolization Coils	Axium™ Helix	III
	Axium™ 3D	III
	Axium™ Nylon Helix	III
	Axium™ PGLA Helix	III
	Axium™ PGLA 3D	III
	Axium™ Prime Bare Platinum Helix	III
	Axium™ Prime Bare Platinum 3D	III
	Axium™ Prime Frame Complex	III
	Concerto™ Bare Platinum Helix	IIb
	Concerto™ Bare Platinum 3D	IIb
	Concerto™ PGLA Fiber Helix	III
	Concerto™ PGLA Fiber 3D	III
	Concerto™ Nylon Fiber Helix	IIb
Neurovascular Remodeling Devices	Solitaire™ AB Neurovascular Remodeling Device	III
	Pipeline™ Flex Embolization Device (PFED)	III
	Pipeline™ Flex Embolization Device with Shield Technology™ (SHIELD)	III
	Pipeline™ Vantage Embolization Device with Shield Technology™ (PED3)	III
Detachment Devices	Solitaire™ NDS-2x Detachment System	IIa
	Cable Set Sterile (NCS),	Is
	Solitaire Cable Set (CSS),	Is
	Instant Detacher (I.D.)	Is
	Artisse™ Detachment Device	IIa
Revascularization Devices	Solitaire™ 2 Revascularization Device	III
	Solitaire™ Platinum Revascularization Device	III
	Solitaire™ X Revascularization Device	III
Liquid Embolic Systems	Onyx™ Liquid Embolic System (LES)	III
Infusion Catheters	Cragg McNamara™ Catheter	IIb
	MicroMewi™ Infusion Catheter	IIb
Infusion Wires	ProStream™ Infusion Wire	IIb
Balloon Occlusion Catheters	HyperGlide™ Occlusion Balloon System	III
	HyperForm™ Occlusion Balloon System	III

This annex is only valid in connection with the above-mentioned certificate.

Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170773730
Effective date: 2021-01-04

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

Device family	Device	Class
Syringe Adapters, Syringes and Introducer Sheaths	Echelon™ Syringe Adapter	Is
	Cadence™ Precision Injector Accessory	Is
	Onyx™ Syringe Catheter Interface Adapter	Is
	1mL Syringe	Is
Guide Wires	Mirage™ Hydrophilic Guidewire	III
	X-Pedion™ Hydrophilic Guidewire	III
	Avigo™ Hydrophilic Guidewire	III
Micro Catheters	Marksman™ Catheter	III
	Nautica™ Micro Catheter	III
	Echelon™ Micro Catheter	III
	Rebar™ Micro Catheter	III
	Orion™ Micro Catheter	III
	Phenom™ Catheter	III
Flow Directed Catheters	Marathon™ Flow Directed Micro Catheter	III
	Apollo™ Onyx™ Delivery Micro Catheter	III
Guide Catheter	Navien™ A+ Intracranial Catheter	III
	React™ 68 Catheter	III
	React™ 71 Catheter	III
	Rist™ Radial Access Selective Catheter	III
	Rist™ 079 Radial Access Guide Catheter	III
Surgical irrigation/aspiration system	Riptide™ Aspiraton Pump	IIa
	Riptide™ Large Bore Aspiration Tubing	Is
Embolization Devices	Artisse™ Intrasaccular Device	III

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA, 92618
United States of America

that the design of the following device(s)

Rebar™ Micro Catheters

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 281863 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: STED18-003 Rebar STED Redlines_Oct18 dated 2018-10-27

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 411_18e_Report_TFR_Rebar_V1 dated 2018-11-11

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	489932 MRA
Certificate unique ID	170727184
Effective date	2018-12-18
Expiry date	2023-12-17
Frankfurt am Main	2018-11-12

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.

EU MDR Declaration of Conformity (DoC)

Manufacturer:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 United States
Manufacturer SRN:	US-MF-000019796
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany Notified Body Number: 0297
Conformity Assessment Certificate(s):	EU-Quality Management Certificate ID: 170777415 EU-Examination Certificate ID: 170779532
Conformity Assessment Procedure:	Annex IX
Risk Class:	III
Classification Rule:	Rule 7, Sub-section 2
Intended Purpose:	The Solitaire™ X Revascularization Device is designed for use in the flow restoration of patients with ischemic stroke due to large intracranial vessel occlusion. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Statement:

We, Micro Therapeutics, Inc. d/b/a ev3 Neurovascular (a wholly owned subsidiary of Medtronic Inc.), hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

Union Legislation	Applicable Declaration of Conformity Document Number
Not Applicable	Not Applicable

Place: Irvine, CA

Name: Kara Madsen

Title: Sr. Director Regulatory Affairs

Signature:

Date: *30 March 2022*

Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g., GMDN)
	CFN		
Solitaire™ X Revascularization Device	SFR4-3-20-10	8475360B0000001S5	GMDN 61779– Thrombectomy wire-net
	SFR4-3-40-10	8475360B0000001S5	

Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
EN ISO 13485	2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971	2012	Medical Devices – Application of Risk Management to Medical Devices
ANSI/AAMI HE75	2009(R2013)	Human Factors Engineering – Design of Medical Devices
EN ISO 14644-1	2015	Cleanrooms and Associated Controlled Environments – Part 1: Classification of Air Cleanliness by Particle Concentration
EN ISO 14644-2	2015	Cleanrooms and Associated Controlled Environments – Part 2: Monitoring to Provide Evidence of Cleanroom Performance Related to Air Cleanliness by Particle Concentration
EN ISO 14644-3	2005	Cleanrooms and Associated Controlled Environments – Part 3: Test Methods
EN ISO 14644-4	2001	Cleanrooms and Associated Controlled Environments – Part 4: Design, Construction and Start-Up
EN ISO 14644-5	2004	Cleanrooms and Associated Controlled Environments – Part 5: Operations
EN ISO 14698-1	2003	Cleanrooms and Associated Controlled Environments – Biocontamination Control – Part 1: General Principles and Methods
EN ISO 14698-2	2003/AC:2006	Cleanrooms and Associated Controlled Environments – Biocontamination Control – Part 2: Evaluation and Interpretation of Biocontamination Data
ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
USP 788	2014	Particulate Matter in Injections
EN ISO 11607-1	2020	Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
EN ISO 11607-2	2020	Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
ASTM F88	2015	Standard Test Method for Seal Strength of Flexible Barrier Materials

Number	Date of Issue	Title
ASTM F2096	2011	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ISTA 2A	2012	Partial Simulation Test Procedure for individual Packaged-Products 150 lbs or less
ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1929	2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2203	2013	Standard Test Method for Linear Measurement Using Precision Steel Rule
ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
EN ISO 15223-1	2016/Amd 2017	Medical Devices – Symbols to be used with Medical Device Labels, Labelling, and Information to be Supplied – Part 1: General Requirements
EN 1041	2008 +A1:2013	Information Supplied by the Manufacturer of Medical Devices
EN ISO 11135	2014	Sterilization of Health Care products: Ethylene Oxide
ISO 11138-1	2017	Sterilization of Health Care Products – Biological indicators – Part 1: General Requirements
EN ISO 11138-2	2017	Sterilization of Health Care Products – Biological Indicators – Part 2: Biological Indicators for Ethylene Oxide Sterilization Process
ISO 14161	2009	Sterilization of Health Care Products – Biological Indicators – Guidance for the Selection, Use and Interpretation of Results
AAMI/ANSI ST72	2011(R2016)	Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing
EN ISO 11737-1	2018	Sterilization of Health Care Products – Microbiological Methods – Part 1: Determination of the Population of Microorganisms of Product

Number	Date of Issue	Title
EN ISO 11737-2	2009	Sterilization of Medical Devices – Microbiological methods – Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process
EN ISO 10993-1	2009/AC:2010	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
EN ISO 10993-3	2014	Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
EN ISO 10993-4	2009	Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interaction with Blood
EN ISO 10993-5	2008	Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
EN ISO 10993-7	2008/AC2009	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
ISO 10993-10	2010	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
EN ISO 10993-11	2009	Biological Evaluation of Medical Devices – Part 11: Tests Systemic Toxicity
EN ISO 10993-12	2012	Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Sample Materials

EU Quality Management Certificate

This is to certify that the company

Micro Therapeutics Inc, d/b/a Ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

SRN: US-MF-000019796

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the product categories and products listed in the Annex.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Certificate registration no.	281863 MDR2017Q
Certificate ID	170780189
Effective date	2022-06-10
Expiry date	2027-03-23
Frankfurt am Main,	2022-06-10

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG
DQS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.

420.90 Version 2.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: SRN: US-MF-000019796
Certificate ID: 170780189

Authorised Representative of the company:

EU Representative

Medtronic BV
B.V.,Earl Bakkenstraat 10
6422 PJ Heerlen,
The Netherlands

SRN of EU Representative: NL-AR-000006050

Device categories covered by this certificate:

Device category:	Vascular Microcatheter
Risk classification:	III
Intended purpose:	The Catheters are intended for the introduction of interventional devices or diagnostic agents into the neuro, peripheral, and coronary vasculatures.
Device category:	Thrombectomy wire-net
Risk classification:	III
Intended purpose:	The Solitaire™ X Revascularization Device is designed for use in the flow restoration of patients with ischemic stroke due to large intracranial vessel occlusion. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Device category:	Suction system tubing, single-use
Risk classification:	Is
Intended purpose:	The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Device category:	Vascular implant detacher, single-use, sterile
Risk classification:	Is
Intended purpose:	The Instant Detacher (I.D.) is intended for use with the compatible detachable coil devices (Axium, Axium Prime, Concerto and Concerto Versa) for the corresponding device indication for use.
Device category:	Electrical-only medical device connection cable, single-use
Risk classification:	Is
Intended purpose:	The Solitaire™ Detachment System is intended for use with the Solitaire™ AB device. The Solitaire™ Detachment System is not intended to be used with coils.
Device category:	IV line/syringe luer connector
Risk classification:	Is
Intended purpose:	The Onyx™ Syringe-Catheter Interface-Adapter (SCIFA) is intended for use as an accessory to the Onyx™ Liquid Embolic System (LES) and Marathon™ Micro Catheter during Onyx™ LES injection.

This annex is only valid in connection with the above-mentioned certificate.

Annex to EU Quality Management Certificate
SRN of Manufacturer: SRN: US-MF-000019796
Certificate ID: 170780189

Device category:	Catheter-balloon inflator, single-use
Risk classification:	Is
Intended purpose:	The Cadence™ Precision Injector is intended for the controlled delivery of fluids in the inflation and deflation of temporary occlusion balloons.
Device category:	General-purpose syringe, single use
Risk classification:	Is
Intended purpose:	The device is indicated for the injection or aspiration of fluids to or from the body. This is a general-purpose syringe.
Device category:	Surgical irrigation/aspiration system
Risk classification:	IIa
Intended purpose:	The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment..
Device category:	Vascular embolization coil detacher, single-use
Risk classification:	IIa
Intended purpose:	"The Artisse™ Detachment Device is intended for use only with the Artisse™ Intrasaccular Device."

Examinations and tests performed:
2021-11-07_A209224MED_MicroTherapeuticsInc.dbaev3neurovascular_420_11e_Report_MED dated 2022-03-12

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.
Products of class IIa, class IIb as well as class III listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297).

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-03-24	170777415	Adding Is devices and IIa devices to certificate in accordance with sampling plan

This annex is only valid in connection with the above-mentioned certificate.

EU-Examination Certificate

This is to certify that the company

Micro Therapeutics, Inc.

9775 Toledo Way
Irvine, CA, 92618
United States of America

EU-Representative

Medtronic B.V.,
Earl Bakkenstraat 10,
6422 PJ Heerlen,
Netherlands

has implemented a complete Quality Management System for each phase from Design to Final Testing of the products.

Through an audit, documented in a report, carried out by DQS Medizinprodukte GmbH, the proof was provided that this quality management system meets the requirements according to

Annex IX of the Regulation (EU) 2017/745

CONFORMITY ASSESSMENT PROCEDURE ON THE BASIS OF A QUALITY MANAGEMENT SYSTEM AND AN ASSESSMENT OF THE TECHNICAL DOCUMENTATION

regarding the medical devices listed in the Annex:
The manufacturer shall be subject to surveillance in accordance with Annex IX, Chapter 1, Section 3.
The CE marking with the identification number of the Notified Body (0297) may be affixed on the devised listed on the certificate.

Certificate registration no.	US-MF-000019796
Certificate ID	170779532
Previous certificate-ID	n/a
Effective date	2022-03-17
Expiry date	2027-03-16
Frankfurt am Main,	2022-03-17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

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 Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.

420.92 Version 1.0

Annex to EU-Examination Certificate
Certificate registration No.: US-MF-000019796
Certificate ID: 170779532
Effective date: 2022-03-17

Micro Therapeutics, Inc.

5290 California Avenue
Irvine, CA 92617
United States of America

Product name	Model	Type	Intended Use	Risk class	Basic UDI-DI
Solitaire X Revascularization Device 3X20mm	SFR4-3-20-10	n/a	The Solitaire™ X Revascularization Device is designed for use in the flow restoration of patients with ischemic stroke due to large intracranial vessel occlusion. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.	III	8475360B0000001S5
Solitaire X Revascularization Device 3X40mm	SFR4-3-40-10	n/a	The Solitaire™ X Revascularization Device is designed for use in the flow restoration of patients with ischemic stroke due to large intracranial vessel occlusion. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.	III	8475360B0000001S5

Examinations and tests performed (e.g. Reference to relevant CS, harmonised standards, test reports and audit report):
420_12e_Report_TFR Solitaire X_03 dated 2022-02-24

Reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered:
n/a

Conditions or limitations regarding the validity of the certificate:
n/a

This annex is only valid in connection with the above-mentioned certificate.

EC DECLARATION OF CONFORMITY

General Applicable Directives/Standards:

EN ISO 13485:2016+AC:2016 **Quality Management System Standard** (281863 MP2016)

93/42/EEC
Conformity Assessment Route

Council Directive Concerning Medical Devices
Annex II (excluding Section 4) 281863 MR2
Annex II (Section 4) 545257 MRA

Product	Model/Reference/ Catalogue Number(s)	GMDN Code	Class-Rule	Date CE Mark Affixed
Solitaire™ X Revascularization Device	SFR4-4-20-05	61779, Thrombectomy wire-net	Class III - Rule 7	05AUG19
	SFR4-4-20-10			
	SFR4-4-40-10			
	SFR4-6-20-10			
	SFR4-6-24-06			
	SFR4-6-40-10			

Manufacturer:
Micro Therapeutics, Inc.
DBA ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618 USA

Notified Body:
DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main, Germany
Notified Body Number: 0297

European Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the medical device directive 93/42/EEC as amended by 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Fay Farmand
Sr.Manager, Regulatory Affairs

Irvine, California 92618; USA
Place of Issue

25-OCT-2021
Date of Issue

This Declaration of Conformity expires on 2024-05-26.

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
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:

Implants and Instruments for Interventional Minimal Invasive Therapy according to annex.

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.	281863 MR2
Certificate unique ID	170773730
Effective date	2021-01-04
Expiry date	2024-05-26
Frankfurt am Main	2021-01-04

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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Head of Certification Body

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

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170773730
Effective date: 2021-01-04

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

Device family	Device	Class
Detachable Embolization Coils	Axium™ Helix	III
	Axium™ 3D	III
	Axium™ Nylon Helix	III
	Axium™ PGLA Helix	III
	Axium™ PGLA 3D	III
	Axium™ Prime Bare Platinum Helix	III
	Axium™ Prime Bare Platinum 3D	III
	Axium™ Prime Frame Complex	III
	Concerto™ Bare Platinum Helix	IIb
	Concerto™ Bare Platinum 3D	IIb
	Concerto™ PGLA Fiber Helix	III
	Concerto™ PGLA Fiber 3D	III
	Concerto™ Nylon Fiber Helix	IIb
Neurovascular Remodeling Devices	Solitaire™ AB Neurovascular Remodeling Device	III
	Pipeline™ Flex Embolization Device (PFED)	III
	Pipeline™ Flex Embolization Device with Shield Technology™ (SHIELD)	III
	Pipeline™ Vantage Embolization Device with Shield Technology™ (PED3)	III
Detachment Devices	Solitaire™ NDS-2x Detachment System	IIa
	Cable Set Sterile (NCS),	Is
	Solitaire Cable Set (CSS),	Is
	Instant Detacher (I.D.)	Is
	Artisse™ Detachment Device	IIa
Revascularization Devices	Solitaire™ 2 Revascularization Device	III
	Solitaire™ Platinum Revascularization Device	III
	Solitaire™ X Revascularization Device	III
Liquid Embolic Systems	Onyx™ Liquid Embolic System (LES)	III
Infusion Catheters	Cragg McNamara™ Catheter	IIb
	MicroMewi™ Infusion Catheter	IIb
Infusion Wires	ProStream™ Infusion Wire	IIb
Balloon Occlusion Catheters	HyperGlide™ Occlusion Balloon System	III
	HyperForm™ Occlusion Balloon System	III

This annex is only valid in connection with the above-mentioned certificate.

Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170773730
Effective date: 2021-01-04

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

Device family	Device	Class
Syringe Adapters, Syringes and Introducer Sheaths	Echelon™ Syringe Adapter	Is
	Cadence™ Precision Injector Accessory	Is
	Onyx™ Syringe Catheter Interface Adapter	Is
	1mL Syringe	Is
Guide Wires	Mirage™ Hydrophilic Guidewire	III
	X-Pedion™ Hydrophilic Guidewire	III
	Avigo™ Hydrophilic Guidewire	III
Micro Catheters	Marksman™ Catheter	III
	Nautica™ Micro Catheter	III
	Echelon™ Micro Catheter	III
	Rebar™ Micro Catheter	III
	Orion™ Micro Catheter	III
	Phenom™ Catheter	III
Flow Directed Catheters	Marathon™ Flow Directed Micro Catheter	III
	Apollo™ Onyx™ Delivery Micro Catheter	III
Guide Catheter	Navien™ A+ Intracranial Catheter	III
	React™ 68 Catheter	III
	React™ 71 Catheter	III
	Rist™ Radial Access Selective Catheter	III
	Rist™ 079 Radial Access Guide Catheter	III
Surgical irrigation/aspiration system	Riptide™ Aspiraton Pump	IIa
	Riptide™ Large Bore Aspiration Tubing	Is
Embolization Devices	Artisse™ Intrasaccular Device	III

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA, 92618
United States of America

that the design of the following device(s)

Solitaire™ X Revascularization Device

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 281863 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: NV-STED-SolitaireX_Final_25JUL19.pdf dated 2019-07-25

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 411_18e_Report_TFR_Solitaire X_V1.docx dated 2019-08-05

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	545257 MRA
Certificate unique ID	170747798
Effective date	2019-08-05
Expiry date	2024-05-26
Frankfurt am Main	2019-08-05

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
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