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. 8 din 11.07.2023

Solicitantul FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6, tel./fax: 022-273712, e-mail: contact@datacontrol.md
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:

1) Traxcess
GW1420040
GW1420040S
GW1420040X
GW14100EX

Se anexează următoarele acte:
1) Declarație de Conformitate, din 28.06.2018;
2) Certificarte CE no. 411133MR2 din 29.04.2021.
3) Actul prin care producătorul își desemnează reprezentantul din 08.07.2021

Data 11.07.2023 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 Grabazei Alexandru
Date: 2023.07.12 09:36:38 EEST
Reason: MoldSign Signature
Location: Moldova

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6

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:

1) **Traxcess**
   GW1420040
   GW1420040S
   GW1420040X
   GW14100EX

Se anexează următoarele acte:
1) Declarație de Conformitate, din 28.06.2018;
2) Certificarte CE no. 411133MR2 din 29.04.2021.
3) Actul prin care producătorul își desemnează reprezentantul din 08.07.2021

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Grabazei Alexandru, director general. *Data 11.07.2023*

Str. Grigore Mora nr.34, sector 1, Bucuresti
Tel/Fax: 021 12 37 38 Tel/Fax: 021 211 48 49
Email: office@tecmed.ro

SCRISOARE DE AUTORIZARE

08.07.2021

Subscrisa **SC.TECMED SRL**, RO1578232, J40/2946/1992, cu sediul social in Str. Dr. Grigore Mora 34, sector 1, Bucuresti, Romania 01188 si punct de lucru Str. Gheorghe Bratianu nr.30, parter, sector 1, Bucuresti, Romania 011413, **"FURNIZOR DISPOZITVE MEDICALE"**,

Prin prezenta numesc **"SUB-DISTRIBUITOR"**: FCPC "DataControl" SRL cu sediul in Str. Melestiu nr.20, MD-2001, Chisinau, Republic Moldova autorizat sa inregistreze, sa re-inregistreze sau sa aduca modificari dispozitivelor inregistrate, sa comercializeze si sa promoze urmatoarele dispozitive cu marcaj CE, conform Contractului de Sub-distributie E55 nr. din 15.06.2019 si Anexele in vigoare:

- Portofoliu neurovascular **MicroVention – produse noi:**

Microghiduri neurovasculare: TRAXCESS 7 MINI

Microcatetere neurovasculare: WEDGE

Catetere de acces distal cu aspiratie: SOFIA EX

Micro Balon cu dublu-lumen: SCEPTER MINI

Stent intraluminal: LVIS EVO

Stent revascularizare: FRED X

Prin prezenta FCPC "DataControl" SRL este autorizata sa inregistreze dispozitivele sus-numite la autoritatile competente conform legislatiei in vigoare in Republica Moldova. Certificatele de inregistrare vor fi emise in numele SC. TECMED SRL, conform documentelor de calitate emise de producatorul MICROVENTION.

Scrisoare de Autorizare este valabila pentru o perioada de 24 de luni de la data semnarii acestui document, daca nu este revocat intre timp de catre una dintre parti.

TECMED SRL

Gheorghe Diaconu,
Administrator

Societatea Comerciala TECMED S.R.L. Romania

TECMED S.R.L.
INTRARE/IEŞIRE NR. 105
Ziua 08 Luna 07 Anul 2021

EC DECLARATION OF CONFORMITY

FD08-001, Rev. R

We, MicroVention, Inc., located in Tustin, California, USA declare according to Directive 93/42/EEC Annex II (incl. section 4.) under our sole responsibility that the products to which this declaration relates are in conformity with Directive 93/42/EEC and fulfill the Essential Requirements as described in Directive 93/42/EEC Annex I.

Directives 93/42/EEC Council Directive Concerning Medical Devices
Conformity Assessment Route
EC Design Examination: 411133 MRA (Section 4)
Full Quality Assurance: 411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
Traxcess 14 Guidewire*	GW1420040	III – Annex IX, Rule 7, Subclause 1	2018-05-27	35094
Traxcess 14EX Guidewire*	GW1420040X			
Traxcess 14 SELECT Guidewire	GW1420040S			
Traxcess 7 Mini	GW0721006M			
Traxcess 7 Mini XSoft	GW0721006S			
Traxcess Docking Wire*	GW14100EX	IIa- Annex IX, Rule 7		61281

Manufacturer/ Production Site:
MicroVention Inc,
1311 Valencia Avenue
Tustin, CA 92780 USA

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

EU Representative:
MicroVention Europe
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

Production Site:
Ashitaka Factory of Terumo Corp. *
150 Maimaigi-Cho
Fujinomiya, Sizuoka Japan

Intended Use: The Traxcess Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

We herewith declare that the above-mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Sal Palomares
Regulatory Affairs Director
MicroVention, Inc.

Tustin, CA 92780, USA
Place of Issue

28 June 2018
Date of Issue

Expiry Date: 2023-05-26
Prepared for Romania

DCMicroVention Inc. 1311 Valencia Avenue, Tustin, California, 92780, USA
Tel : 714-247-8000 – Fax : 714-247-8005 www.microvention.com

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
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:

Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires) and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices, and Detachment Controller Units as listed in 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.	411133 MR2
Certificate unique ID	170776096
Effective date	2021-04-29
Expiry date	2024-05-26
Frankfurt am Main	2021-04-29

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.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Production Sites:

1.
MicroVention, Inc.
35 Enterprise,
Aliso Viejo, CA 92656
United States of America

2.
MicroVention, Inc.
1311 Valencia Ave.
Tustin, CA 92780
United States of America

3.
MicroVention Costa Rica, S.R.L.
Zona Franca Coyol
Alajuela,
Costa Rica

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolization Prothese	MicroPlex Coil System (MCS) & HydroCoil Embolic System (HES) with V-Trak Delivery System	MicroPlex 10 Platinum Coil System (MCS) Endovascular Embolization Coil - Cosmos10 - HyperSoft 3D - HyperSoft Helical - Helical 10 - VFC - Compass 10 - Complex 10	III	1,2,3
		MicroPlex 18 Platinum Coil System (MCS) Endovascular Embolization Coil - Cosmos 18 - Helical 18 - Compass 18 - Complex 18	III	1,2,3
		HydroCoil 10 Embolic System (HES) Endovascular Embolization Coil - HydroFrame 10 - HydroSoft Helical - HydroSoft 3D - HydroFill	III	1,2,3
		HydroCoil 18 Embolic System (HES) Endovascular Embolization Coil - HydroFrame 18	III	1,2,3
	AZUR® Peripheral Coil System	AZUR® HydroCoil Detachable Embolization Coils 18 & 35	IIb	1,2,3
		AZUR® HydroCoil Pushable Embolization Coils 18 & 35	IIb	1,2,3
		AZUR® Framing Detachable Coils 18 & 35	IIb	1,2,3
		AZUR® Injectable Coil System 18 & 35	IIb	1,2,3
		AZUR Detachable 18	IIb	1,2,3
		AZUR PURE Pushable Coil System 18 & 35	IIb	1,2,3
		AZUR CX Detachable 18 & 35	IIb	1,2,3
		AZUR Vascular Plug	IIb	1,2,3

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Detachment Controller Units		V-Grip® Detachment Controller	IIa	1,2
		V-Grip® PLUS Detachment Controller	IIa	1,2
		WEB Detachment Controller	IIa	1,2
		AZUR® Detachment Controller	IIa	1,2
Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires)		Traxcess® 14 Guidewire	III	1,2
		Traxcess® 14 EX Guidewire	III	1,2
		Traxcess® 14 SELECT Guidewire	III	1,2
		Traxcess® 7 Mini Guidewire	III	1,2
		Traxcess® 7 Mini XSoft Guidewire	III	1,2
		Traxcess® Docking Wire	IIa	1,2
		Chaperon® Guiding Catheter System	III	2
		Headway® 17 Advanced Soft Microcatheter	III	1,2,3
		Headway® 17 Advanced Microcatheter	III	1,2,3
		Headway® 21 Microcatheter	III	1,2,3
		Headway® 27 Microcatheter	III	1,2,3
		Headway Duo Microcatheter	III	1,2,3
		Scepter C™ Occlusion Balloon Catheter	III	1,2,3
		Scepter XC™ Occlusion Balloon Catheter	III	1,2,3
		Scepter Mini™ Occlusion Balloon Catheter	III	1,2,3
		SOFIA™ Distal Access Catheter	III	1,2,3
		SOFIA™ Select Catheter	III	1,2,3
		SOFIA™ PLUS Catheter	III	1,2,3
		SOFIA™ Flow PLUS Catheter	III	1,2,3
		SOFIA™ Guiding Catheter	III	1,2,3
		SOFIA™ Flow Catheter	III	1,2,3
		SOFIA® EX Catheter	III	1,2,3
		KANSHAS Drug Coated Balloon	III	1
		VIA™ 17 Microcatheter	III	1,2
		VIA™ 21 Microcatheter	III	1,2
		VIA™ 27 Microcatheter	III	1,2
		VIA™ 33 Microcatheter	III	1,2
		Wedge Microcatheter	III	1,2,3
		PG Pro Microcatheter	IIa	1,2,3

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Stents		LVIS™ Intraluminal Support Device	III	1,2,3
		LVIS™ Jr. Intraluminal Support Device	III	1,2,3
		LVIS™ EVO™ Intraluminal Support Device	III	1,2,3
		LVIS™ X™ Intraluminal Support Device	III	1,2,3
		LVIS™ Jr. X™ Intraluminal Support Device	III	1,2,3
		LVIS™ EVO™ X™ Intraluminal Support Device	III	1,2,3
		FRED™ Flow Re-Direction Endoluminal Device	III	1,2,3
		FRED Jr.™ Flow Re-Direction Endoluminal Device	III	1,2,3
		FRED X™ Flow Re-Direction Endoluminal Devices	III	1,2,3
		FRED OMEGA™ Flow Re-Direction Endoluminal Devices	III	1,2,3
		CASPER™ RX Carotid Artery Stent System	III	1,2,3
		Roadsaver Carotid Artery Stent System	III	1,2,3
Peripheral Vascular Stent System		RENZAN™ Peripheral Vascular Stent System	IIb	1,2,3
Clot Retriever		ERIC™ Retrieval Device	III	1,2,3
Liquid Embolic System		PHIL™ Liquid Embolic System	III	1,2
Microspheres		HydroPearl Microspheres	IIb	1,2
		LifePearl Microspheres	III	1,2
		BioPearl® Microspheres	III	1

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

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Tustin, CA, 92780
United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolic Protection Device (EPS)		Empro Embolic Protection System	III	1,3
		Nanoparasol Embolic Protection System	III	1,3
Aneurysm Embolization Device		WEB™ Aneurysm Embolization System	III	1,2
Aspiration Kit		Aspiration Tubing Kit	Is	1,2
		Aspiration Syringe Kit	Is	1,2
BOBBY™ Balloon Guide Catheter		BOBBY™ Balloon Guide Catheter	III	1,2