

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

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 2 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 și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1) Sofia

DA5115ST, DA5125ST,
DA6115ST
AC6115ST, AC6125ST,
AC6131ST, DA6125ST,
DA6131ST, DA6135ST
DA6125ST, DA6131ST
DA5115ST, DA5125ST,
AC5115ST, AC5125ST
ISC5105ST, ISC5115ST

Se anexează următoarele acte:

- 1) Declarație de Conformitate, din 11.19.2020;
- 2) Certificate CE no. 411133 MR2 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	

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE 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. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- 1) Declarație de Conformitate, din 30.05.2019;
- 2) Certificarte CE no. 411133 MR2 din 29.04.2021.
- 3) Actul prin care producătorul își desemnează reprezentantul din 08.07.2021

Sunt autentice și corespund realității.

Numele, prenumele și funcția

Grabazei Alexandru, director general.

Semnătura _____

Data 11.07.2023

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-DISTRIBUTOR"**: 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 promoveze 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





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.



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
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MicroVention, Inc.

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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	III	1,2,3
		- Cosmos10		
		- HyperSoft 3D		
		- HyperSoft Helical		
	MicroPlex 18 Platinum Coil System (MCS) Endovascular Embolization Coil	- Helical 10	III	1,2,3
		- VFC		
		- Compass 10		
		- Complex 10		
	HydroCoil 10 Embolic System (HES) Endovascular Embolization Coil	- Cosmos 18	III	1,2,3
		- Helical 18		
		- Compass 18		
		- Complex 18		
	HydroCoil 18 Embolic System (HES) Endovascular Embolization Coil	HydroCoil 10 Embolic System (HES) Endovascular Embolization Coil	III	1,2,3
		- HydroFrame 10		
		- HydroSoft Helical		
		- HydroSoft 3D		
	AZUR® Peripheral Coil System	- HydroFill	III	1,2,3
		HydroCoil 18 Embolic System (HES) Endovascular Embolization Coil		
		- HydroFrame 18		
		AZUR® HydroCoil Detachable Embolization Coils 18 & 35		
		AZUR® HydroCoil Pushable Embolization Coils 18 & 35	IIb	1,2,3
		AZUR® Framing Detachable Coils 18 & 35		
		AZUR® Injectable Coil System 18 & 35		
		AZUR Detachable 18		
		AZUR PURE Pushable Coil System 18 & 35	IIb	1,2,3
		AZUR CX Detachable 18 & 35		
		AZUR Vascular Plug		

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



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Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Detachment Controller Units		V-Grip® Detachment Controller	Ila	1,2
		V-Grip® PLUS Detachment Controller	Ila	1,2
		WEB Detachment Controller	Ila	1,2
		AZUR® Detachment Controller	Ila	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	Ila	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	Ila	1,2,3



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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

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

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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

EC DECLARATION OF CONFORMITY

RF 19-0097 Rev.B

DC Number: 20-05340

We, MicroVention Europe SARL, located in Saint-Germain-en-Laye, France, declare according to Directive 93/42/EEC Annex II 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.

Council Directive 93/42/EEC

Conformity Assessment Procedure Performed:

EC Design Examination Certificate ☒ <u>(Annex II.4)</u> 487703 MRA Certificate Number	EC Full Quality Assurance Certificate ☒ <u>(Annex II.3)</u> 487703 MR2 Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
SOFIA® Distal Access Catheter	DA5115ST, DA5125ST, DA6115ST	III – Annex 9, rule 7	58173 (Thrombectomy catheter)
SOFIA® PLUS Catheter	AC6115ST, AC6125ST, AC6131ST, DA6125ST, DA6131ST, DA6135ST		58173 (Thrombectomy catheter)
SOFIA® Flow PLUS Catheter	DA6125ST, DA6131ST		58173 (Thrombectomy catheter)
SOFIA® Flow Catheter	DA5115ST, DA5125ST, AC5115ST, AC5125ST		58173 (Thrombectomy catheter)
SOFIA® EX Catheter	ISC5105ST, ISC5115ST		17846 (Vascular guide catheter, Single Use)

Legal Manufacturer	Production Site(s)	Notified Body
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	MicroVention, Inc. 1311 Valencia Avenue Tustin, California 92780 USA MicroVention, Inc. 35 Enterprise Aliso Viejo, California 92656 USA MicroVention Costa Rica, S.R.L. Zona Franca Coyol Alajuela, Costa Rica	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297

EC DECLARATION OF CONFORMITY

We herewith declare that the above-mentioned medical device (s) meet the provisions of the council directive 93/42/EEC Medical Device Directive. This declaration is supported by the EC Quality System Certificate (s) according to the provisions of the relevant Annex (es) of above Directive. This declaration applies to all device(s) specified above distributed from the signature date forward.

DocuSigned by:

Signer Name: Irina Kulinets
Signing Reason: I approve this document
Signing Time: 11/19/2020 | 6:28:42 PM PST
F47F956B62B5424CBF023EA37BA8F01F

Saint-Germain-en-Laye,
France

11/19/2020

Irina Kulinets
Sr. Vice President, Regulatory
Affairs, Quality, Clinical Research
MicroVention Europe SARL

Place of Issue

Date of Issue

Certificate Expiry Date: 2024-05-26