

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 21.09.2023

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) **Traccess 14**
GW1420040
- 2) **Traccess 14EX**
GW1420040X
- 3) **Traccess 14 SELECT**
GW1420040S
- 4) **Traccess 7 Mini**
GW0721006M
- 5) **Traccess 7 Mini XSoft**
GW0721006S
- 6) **Traccess 14EX**
GW14100EX

Se anexează următoarele acte:

- 1) Declarație de Conformitate, nr. RF19-0078 Rev. D din 24.08.2022;
- 2) Certificarte CE no. 411133 MR2 din 29.04.2021.
- 3) Certificarte CE-Design no. 411133 MRAdin 03.03.2020.
- 4) Actul prin care producătorul își desemnează reprezentantul

Data 21.09.2023

Semnătura _____

Tablelul 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	

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) **Traccess 14**
GW1420040
- 2) **Traccess 14EX**
GW1420040X
- 3) **Traccess 14 SELECT**
GW1420040S
- 4) **Traccess 7 Mini**
GW0721006M
- 5) **Traccess 7 Mini XSoft**
GW0721006S
- 6) **Traccess 14EX**
GW14100EX

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- 4) Actul prin care producătorul își desemnează reprezentantul

Sunt autentice și corespund realității.

Numele, prenumele și funcția

Semnătura _____

Grabazei Alexandru, director general.

Data 21.09.2023



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



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MicroVention, Inc.

1311 Valencia Ave.
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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			
			- Helical 10		
			- VFC		
			- Compass 10		
			- Complex 10		
			MicroPlex 18 Platinum Coil System (MCS) Endovascular Embolization Coil	III	1,2,3
			- Cosmos 18		
		- Helical 18			
		- Compass 18			
		- Complex 18			
		HydroCoil 10 Embolic System (HES) Endovascular Embolization Coil	III	1,2,3	
		- HydroFrame 10			
		- HydroSoft Helical			
		- HydroSoft 3D			
		- HydroFill			
		HydroCoil 18 Embolic System (HES) Endovascular Embolization Coil	III	1,2,3	
		- HydroFrame 18			
	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	

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
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

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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

RF19-0078 Rev. D
ECN Number: 22-03348

We, MicroVention, Inc., located in Aliso Viejo, California, USA, 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 <input checked="" type="checkbox"/> <u>(Annex II.4)</u> <hr/> 411133 MRA Certificate Number	EC Full Quality Assurance Certificate <input checked="" type="checkbox"/> <u>(Annex II.3)</u> <hr/> 411133 MR2 Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
Traxcess 14 Guidewire*	GW1420040	Class III, Annex 9, Rule 7	35094
Traxcess 14EX Guidewire*	GW1420040X		
Traxcess 14 SELECT Guidewire	GW1420040S		
Traxcess 7 Mini	GW0721006M		
Traxcess 7 Mini XSoft	GW0721006S		
Traxcess Docking Wire*	GW14100EX	Class IIa, Annex 9, Rule 7	61281

Legal Manufacturer	Production Site(s)	Notified Body	EU Representative
MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 United States of America	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 USA *Ashitaka Factory of Terumo Corp. 150 Maimaigi-Cho Fujinomiya, Sizuoka Japan	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297	MicroVention Europe SARL 30 bis, rue du Vieil Abrevoir 78100 Saint-Germain-en-Laye France

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.

EC DECLARATION OF CONFORMITY

DocuSigned by:
Amy Smith
Signer Name: Amy Smith
Signing Reason: I approve this document
Signing Time: 8/24/2022 | 3:15:49 PM PDT
6A007ED64EB548AE8E3F9AB77A2F27F6

Aliso Viejo, CA, USA

8/24/2022

Amy Smith
VP, Global Regulatory Affairs
MicroVention, Inc.

Place of Issue

Date of Issue

Certificate Expiry Date: 2024-05-26

SCRISOARE DE AUTORIZARE

E23.131 / 05.06.2023

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 reinnoim ca "**SUB-DISTRIBUITOR**": FCPC "**DataControl**" SRL cu sediul in Str. N. Testemitanu nr.17/6, scara 2, MD-2025, Chisinau, Republica Moldova, autorizat sa inregistreze, sa re-inregistreze sau sa aduca modificari inregistrarilor, 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:

Portofoliul **neurovascular** al producatorului **MicroVention, SUA**

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.

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


.....
Gheorghe Diaconu,



ADMINISTRATOR – Director General
SC. TECMED SRL

TECMED SRL

Sediul social : Bucuresti, Str. Grigore Mora nr.34, sector 1
Inregistrat la Registrul Comertului Bucuresti : J 40/2946/1992

Cont BCR Sector 1 – RO44 RNCB 0072 0497 1273 0001
Cod fiscal : RO 1578232; Capital social : 20.000 lei



EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention, Inc.

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

that the design of the following device(s)

Traxcess® Guidewire

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. 411133 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: ST19-0010 ATraxcess STED dated 2019-09-30

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

Examination report: 411_18e_Report_TFR_Traxcess_R2020_V1 dated 2020-03-03

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

Certificate registration no. 411133 MRA

Certificate unique ID 170766055

Effective date 2020-03-03

Expiry date 2024-05-26

Frankfurt am Main 2020-03-03

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

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Annex to certificate
Certificate registration No.: 411133 MRA
Certificate unique ID: 170766055
Effective date: 2020-03-03

MicroVention, Inc.

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

Categories of devices:

Traxcess Guidewires

Devices:

Traxcess® 14 Guidewire
Traxcess® 14 EX Guidewire
Traxcess® 14 SELECT Guidewire
Traxcess® 7 Mini Guidewire
Traxcess® 7 Mini XSoft Guidewire