

EC DECLARATION OF CONFORMITY

RF19-0102 Rev. G
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 ☒ <u>(Annex II.4)</u> <u>421268 MRA</u> Certificate Number	EC Full Quality Assurance Certificate ☒ <u>(Annex II.3)</u> <u>411133 MR2 (Excluding Section 4)</u> Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
MicroPlex Platinum Coil System HydroCoil Embolic System	Refer to Table 1 below	Class III, Annex 9, Rule 8	60940

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 MicroVention Costa Rica SRL Zona Franca Coyo Alajuela, Costa Rica	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 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.

DocuSigned by:
Amy Smith

Signer Name: Amy Smith
Signing Reason: I approve this document
Signing Time: 8/24/2022 | 3:23:12 PM PDT
6A007ED64EB548AE8E3F9AB77A2F27F6

Amy Smith VP, Global Regulatory Affairs MicroVention, Inc.	Aliso Viejo, CA, USA Place of Issue	8/24/2022 Date of Issue
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Certificate Expiry Date: 2024-05-26

EC DECLARATION OF CONFORMITY

Table 1: Model Numbers

MicroPlex 10 Platinum Coil System Endovascular Embolization Coil										MicroPlex 18 Platinum Coil System Endovascular Embolization Coil			
Cosmos 10	HyperSoft 3D	HyperSoft 3D (continued)	HyperSoft Helical	HyperSoft Helical (continued)	Helical 10 Soft	Helical 10 Soft (continued)	VFC	Compass 10	Complex 10	Cosmos 18	Compass 18	Helical 18 Soft	Complex 18
100202CSSR-V	100102HS3D-V	100312HS3D-V	100101HS-V	100302HS-V	100202HCSR-S-V	100202HC-S-V	VFC010303-V	100203CM-V	100204CC-V	180617CS-V	180409CM-V	180204HC-S-V	180204CC-V
100254CSSR-V	100103HS3D-V	100355HS3D-V	100102HS-V	100303HS-V	100203HCSR-S-V	100203HC-S-V	VFC061020-V	100203CMSR-V	100307CC-V	180619CS-V	180413CM-V	180208HC-S-V	180307CC-V
100306CSSR-V	100106HS3D-V	100358HS3D-V	100103HS-V	100304HS-V	100204HCSR-S-V	100204HC-S-V	VFC061030-V	100254CM-V	100410CC-V	180723CS-V	180511CM-V	180304HC-S-V	180410CC-V
100408CSSR-V	100115HS3D-V	100406HS3D-V	100104HS-V	100306HS-V	100206HCSR-S-V	100206HC-S-V	VFC101530-V	100254CMSR-V	100512CC-V	180827CS-V	180516CM-V	180308HC-S-V	180512CC-V
100412CSSR-V	100152HS3D-V	100408HS3D-V	100105HS-V	100308HS-V	100208HCSR-S-V	100208HC-S-V	VFC101540-V	100304CM-V	100615CC-V	180931CS-V	180612CM-V	180406HC-S-V	180615CC-V
100515CSSR-V	100153HS3D-V	100409HS3D-V	100106HS-V	100310HS-V	100303HCSR-S-V	100303HC-S-V	VFC152040-V	100304CMSR-V	100718CC-V	181036CS-V	180618CM-V	180410HC-S-V	180717CC-V
100518CSSR-V	100154HS3D-V	100412HS3D-V	100151HS-V	100402HS-V	100304HCSR-S-V	100304HC-S-V	VFC152060-V	100355CM-V	100820CC-V	181139CS-V	180721CM-V	180512HC-S-V	180820CC-V
100522CSSR-V	100155HS3D-V	100415HS3D-V	100152HS-V	100403HS-V	100306HCSR-S-V	100306HC-S-V	VFC030606-V	100355CMSR-V	100924CC-V	181243CS-V	180825CM-V	180615HC-S-V	180923CC-V
100618CSSR-V	100202HS3D-V	100510HS3D-V	100153HS-V	100404HS-V	100308HCSR-S-V	100308HC-S-V	VFC030610-V	100408CM-V	101026CC-V	181347CS-V	180928CM-V	180520HC-R-V	181026CC-V
100622CSSR-V	100203HS3D-V	100515HS3D-V	100154HS-V	100406HS-V	100310HCSR-S-V	100310HC-S-V	VFC030615-V	100408CMSR-V		181451CS-V	181030CM-V	180620HC-R-V	181128CC-V
100626CSSR-V	100204HS3D-V	100520HS3D-V	100155HS-V	100408HS-V	100404HCSR-S-V	100404HC-S-V		100412CM-V		181652CS-V	181134CM-V	180730HC-R-V	181231CC-V
100722CSSR-V	100206HS3D-V	100620HS3D-V	100156HS-V	100410HS-V	100406HCSR-S-V	100406HC-S-V		100412CMSR-V		181859CS-V	181237CM-V	180830HC-R-V	181332CC-V
100731CSSR-V	100208HS3D-V	101510HS3D-V	100201HS-V	100506HS-V	100408HCSR-S-V	100408HC-S-V		100510CM-V		182065CS-V	181339CM-V	180930HC-R-V	181434CC-V
100825CSSR-V	100210HS3D-V	102510HS3D-V	100202HS-V	100508HS-V	100410HCSR-S-V	100410HC-S-V		100510CMSR-V		182263CS-V	181443CM-V	181030HC-R-V	181639CC-V
100837CSSR-V	100212HS3D-V	102512HS3D-V	100203HS-V	100510HS-V	100515HCSR-R-V	100515HC-R-V		100516CM-V		182468CS-V	181648CM-V	181230HC-R-V	181844CC-V
100933CSSR-V	100254HS3D-V		100204HS-V	100606HS-V	100520HCSR-R-V	100520HC-R-V		100516CMSR-V			181855CM-V	181430HC-R-V	182050CC-V
101036CSSR-V	100256HS3D-V		100206HS-V	100608HS-V	100615HCSR-R-V	100615HC-R-V		100612CM-V			182060CM-V	181630HC-R-V	
	100258HS3D-V		100208HS-V	100610HS-V	100620HCSR-R-V	100620HC-R-V		100612CMSR-V				181830HC-R-V	
	100304HS3D-V		100251HS-V	100808HS-V	100720HCSR-R-V	100720HC-R-V		100618CM-V				182030HC-R-V	
	100306HS3D-V		100252HS-V	100810HS-V	100730HCSR-R-V	100730HC-R-V		100618CMSR-V					
	100308HS3D-V		100253HS-V		100820HCSR-R-V	100820HC-R-V		100721CMSR-V					
	100310HS3D-V		100254HS-V		100830HCSR-R-V	100830HC-R-V		100824CMSR-V					
			100256HS-V		100920HCSR-R-V	100920HC-R-V		100928CMSR-V					
			100258HS-V		100930HCSR-R-V	100930HC-R-V		101030CMSR-V					
					101030HCSR-R-V	101030HC-R-V							
					100201HC-S-V								

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HydroCoil 10 Embolic System Endovascular Embolization Coil				HydroCoil 18 Embolic System Endovascular Embolization Coil		
HydroFrame 10	HydroSoft Helical	HydroSoft Helical (continued)	HydroSoft 3D	HydroFill	HydroFill (continued)	HydroFrame 18
100405HFRM-V	100101H2HS-V	100506H2HS-V	100202HFRM-V	100202HFIL-V	101030HFIL-V	180619HFRM-V
100408HFRM-V	100102H2HS-V	100508H2HS-V	100254HFRM-V	100203HFIL-V	101120HFIL-V	180723HFRM-V
100410HFRM-V	100103H2HS-V	100510H2HS-V	100306HFRM-V	100204HFIL-V	101130HFIL-V	180827HFRM-V
100412HFRM-V	100104H2HS-V	100515H2HS-V	100102HFRM-V	100206HFIL-V	101140HFIL-V	180931HFRM-V
100415HFRM-V	100105H2HS-V	100520H2HS-V	100103HFRM-V	100304HFIL-V	101220HFIL-V	181036HFRM-V
100510HFRM-V	100151H2HS-V	100606H2HS-V	100152HFRM-V	100306HFIL-V	101230HFIL-V	181139HFRM-V
100515HFRM-V	100152H2HS-V	100608H2HS-V	100153HFRM-V	100404HFIL-V	101240HFIL-V	181243HFRM-V
100519HFRM-V	100153H2HS-V	100610H2HS-V	100154HFRM-V	100406HFIL-V	101330HFIL-V	181347HFRM-V
100520HFRM-V	100154H2HS-V	100615H2HS-V	100203HFRM-V	100408HFIL-V	101340HFIL-V	181445HFRM-V
100612HFRM-V	100155H2HS-V	100620H2HS-V	100204HFRM-V	100410HFIL-V	101350HFIL-V	181546HFRM-V
100619HFRM-V	100201H2HS-V	100715H2HS-V	100206HFRM-V	100508HFIL-V	101430HFIL-V	181644HFRM-V
100623HFRM-V	100202H2HS-V	100720H2HS-V	100208HFRM-V	100510HFIL-V	101440HFIL-V	181850HFRM-V
100626HFRM-V	100203H2HS-V	100730H2HS-V	100210HFRM-V	100515HFIL-V	101450HFIL-V	182048HFRM-V
100715HFRM-V	100204H2HS-V	100815H2HS-V	100256HFRM-V	100606HFIL-V	101630HFIL-V	182245HFRM-V
100723HFRM-V	100206H2HS-V	100820H2HS-V	100258HFRM-V	100608HFIL-V	101640HFIL-V	182450HFRM-V
100728HFRM-V	100208H2HS-V	100830H2HS-V	100304HFRM-V	100610HFIL-V	101650HFIL-V	
100731HFRM-V	100254H2HS-V	100920H2HS-V	100308HFRM-V	100615HFIL-V	101840HFIL-V	
100817HFRM-V	100256H2HS-V	100930H2HS-V	100310HFRM-V	100620HFIL-V	101850HFIL-V	
100826HFRM-V	100304H2HS-V	101020H2HS-V		100710HFIL-V	102040HFIL-V	
100833HFRM-V	100306H2HS-V	101030H2HS-V		100715HFIL-V	102050HFIL-V	
100836HFRM-V	100308H2HS-V			100720HFIL-V	102240HFIL-V	
100931HFRM-V	100310H2HS-V			100820HFIL-V	102250HFIL-V	
100933HFRM-V	100404H2HS-V			100830HFIL-V	102440HFIL-V	
101036HFRM-V	100406H2HS-V			100920HFIL-V	102450HFIL-V	
101139HFRM-V	100408H2HS-V			100930HFIL-V		

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 3 din 12.10.2023

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) MicroPlex 10 Platinum Coil SystemEndovascular Embolization Coil
2) MicroPlex 18 Platinum Coil SystemEndovascular Embolization Coil
Cosmos 10
HyperSoft 3D
HyperSoft 3D
HyperSoft Helical
HyperSoft Helical
Helical 10 Soft
Helical 10 Soft
VFC
Compass10
Complex 10
Cosmos 18
Compass 18
Helical 18 Soft
Complex 18

3) HydroCoil 10 Embolic SystemEndovascular Embolization Coil
4) HydroCoil 18 Embolic SystemEndovascular Embolization Coil
HydroFrame 10
HydroSoft Helical
HydroSoft Helical
HydroSoft 3D
HydroFill
HydroFill
HydroFrame 18

Se anexează următoarele acte:

- 1) Declarație de Conformitate, nr. RF 19-0102 Rev. G din 24.08.2022;
- 2) Certificate CE no. 411133 MR2
- 3) Certificate CE Design no. 421268 MRA
- 4) Actul prin care producătorul își desemnează reprezentantul

Data 12.10.2023

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	

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) MicroPlex 10 Platinum Coil SystemEndovascular Embolization Coil
- 2) MicroPlex 18 Platinum Coil SystemEndovascular Embolization Coil
- Cosmos 10
- HyperSoft 3D
- HyperSoft 3D
- HyperSoft Helical
- HyperSoft Helical
- Helical 10 Soft
- Helical 10 Soft
- VFC
- Compass10
- Complex 10
- Cosmos 18
- Compass 18
- Helical 18 Soft
- Complex 18

- 3) HydroCoil 10 Embolic SystemEndovascular Embolization Coil
- 4) HydroCoil 18 Embolic SystemEndovascular Embolization Coil

HydroFrame 10
HydroSoft Helical
HydroSoft Helical
HydroSoft 3D
HydroFill
HydroFill
HydroFrame 18

Se anexează următoarele acte:

- 1) Declarație de Conformitate, nr. RF 19-0102 Rev. G din 24.08.2022;
 - 2) Certificarte CE no. 411133 MR2
 - 3) Certificarte CE Design no. 421268 MRA
 - 4) Actul prin care producătorul își desemnează reprezentantul
- Sunt autentice și corespund realității.**

Numele, prenumele și funcția

Semnătura _____

Grabazei Alexandru, director general.

Data 12.10.2023



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 170771828

Effective date 2020-09-11

Expiry date 2024-05-26

Frankfurt am Main 2020-09-11

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: 170771828
Effective date: 2020-09-11

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.

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	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® Framing Detachable 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	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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United States of America

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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MicroVention, Inc.

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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
		CASPER™ RX Carotid Artery Stent System	III	1,2,3
Peripheral Vascular Stent System		Roadsaver Carotid Artery Stent System	III	1,2,3
		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



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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

September 9th, 2023

To Whom it may concern

LETTER OF AUTHORIZATION

We, **MICROVENTION EUROPE**, a French limited liability company, with registered address at 30 bis, rue du Vieil Abreuvoir, 78100 Saint-Germain-en-Laye, registered with the Registry of Commerce and Companies in Versailles under the number 440 775 674, a wholly owned subsidiary of MicroVention, Inc., with registered address at 35 Enterprise, Aliso Viejo, CA 92656 USA, a Terumo group Company which develops, manufactures, markets, distributes and sells proprietary, single-use instruments and systems used in interventional neuroradiology to perform minimally invasive treatment of diseased blood vessels.

MicroVention Inc., appointed us as Authorized Representative in the European Territory under 93/42 CEE European regulation and as its exclusive authorized distributor in the EMEA Region (Europe, Middle East and Africa).

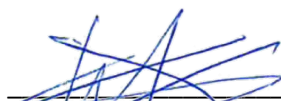
We hereby confirm that **SC TECMED SRL**, a company incorporated under the laws of Romania, having its registered office at 34 Grigore Mora St, Bucharest 011 888 Sector 1, Romania, has been appointed as our authorized distributor for the products listed in Appendix 1 below (the "Products") in the whole territory of Romania and Moldavia (the "Territory") according to a valid distribution agreement.

Thus, SC TECMED SRL is authorized to perform the following in the Territory:

- offer, sell, distribute and deliver the Products; and
- on its own name, participate on public and private bids and tenders.

This Letter of Authorization is valid until March 31st, 2025, unless revoked sooner in writing by Us.

Sincerely,



Sébastien Chabeauti →

Vice President and General Manager, EMEA

APPENDIX 1 – LIST OF PRODUCTS

Product Family
V-Trak® Detachable Embolization Coils System
MicroPlex Platinum Coil System Endovascular Embolization Coils (MCS)
Cosmos 10 & 18
HyperSoft 3D
HyperSoft Helical
Helical 10 & 18
VFC
HydroCoil Embolic System Endovascular Embolization Coils (HES)
HydroFrame 10 & 18
HydroSoft Helical
HydroSoft 3D
HydroFill
Detachment System
V-GRIP Detachment Controller
Microcatheters
Headway 17 Advanced Microcatheter
Headway 21 Microcatheter - 156 cm
Headway 27 Microcatheter - 156 cm
Headway Duo Microcatheter
Wedge Microcatheter
Remodeling Balloons
Scepter C Occlusion Balloon Catheter
Scepter XC Occlusion Balloon Catheter
Scepter Mini Occlusion Balloon Catheter
Scepter™ Mini 0.25mL Syringe
Liquid Embolic
PHIL Liquid Embolic System - Starter kit
PHIL Liquid Embolic System - Refill kit
Embolic Protection device
EMPRO Embolic protection System

Product Family
Guiding Catheters
Chaperon Guiding Catheter System
Chaperon Guiding Catheter Single
Microwires Guidewire
Traxcess 14 Guidewire
Traxcess EX Guidewire
Traxcess Docking Wire
Traxcess SELECT Guidewire
Traxcess 7 Mini Guidewire
WEB Intravascular Flow Disruptor
WEB Aneurysm Embolization System
Via Microcatheter
WEB Detachment Controller
Intracranial Stents
LVIS Intraluminal Support Device
LVIS Jr. Intraluminal Support Device
LVIS EVO Intraluminal Support Device
Flow Diverters
FRED Flow Re-Direction Endoluminal Devices
FRED Jr. Flow Re-Direction Endoluminal Devices
FRED X Flow Re-Direction Endoluminal Devices
Distal Access Catheter
SOFIA Distal Access Catheter (5&6F - 115 cm)
SOFIA EX Catheter
Stroke Aspiration
SOFIA Flow & SOFIA PLUS Catheters (5&6F 125cm-131cm)
Aspiration Tubing Kit
Aspiration Syringe Kit
Carotid Stent
CASPER Carotid Artery Stent
Stroke Stentriever
ERIC Retrieval Device