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:

V-Grip Detachment Controller	**VG501**
Azur Detachment Controller	**45-4001**
WEB Detachment Controller	**WDC-1**
	WDC-2

Se anexează următoarele acte:

1) Declarație de Conformitate, nr. RF 20-0014 Rev. B din 08.08.2022;
2) Certificarte CE no. 411133 MR2
3) Actul prin care producătorul își desemnează reprezentantul

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Grabazei Alexandru, director general. *Data 12.10.2023*

Digitally signed by Grabazei Alexandru
Date: 2023.10.13 15:42:46 EEST
Reason: MoldSign Signature
Location: Moldova

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.

411.20 Version 1.0

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
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

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: 170771828
Effective date: 2020-09-11

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: 170771828
Effective date: 2020-09-11

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
		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: 170771828
Effective date: 2020-09-11

MicroVention, Inc.

1311 Valencia Ave.
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

EC DECLARATION OF CONFORMITY

RF20-0014 Rev. B
ECN Number: 22-03389

We, MicroVention, Inc., located in Tustin, 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 ☐ (Annex II.4) Not Applicable **Certificate Number**	**EC Full Quality Assurance Certificate** ☐ (Annex II.3) 411133 MR2 (excluding Sect. 4) **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
V-Grip Detachment Controller Azur Detachment Controller WEB Detachment Controller	VG501 45-4001 WDC-1 WDC-2	IIa – Annex IX, rule 9	60637

Legal Manufacturer	Production Site(s)	Notified Body	EU Representative
MicroVention, Inc. 1311 Valencia Ave. Tustin, CA, 92780 USA	MicroVention Inc. 1311 Valencia Ave. 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 (V-Grip, Azur only)	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.

MicroVention Inc., 35 Enterprise, Aliso Viejo, California, 92656, USA
Tel : 714-247-8000 – Fax : 714-247-8005 www.microvention.com

EC DECLARATION OF CONFORMITY

DocuSigned by:
Amy Smith
Signer Name: Amy Smith
Signing Reason: I approve this document
Signing Time: 8/8/2022 | 10:20:56 AM PDT
6A007ED64EB548AE8E3F9AB77A2F27F6

	Tustin, CA, USA	8/8/2022
Amy Smith VP, Global Regulatory Affairs MicroVention, Inc.	Place of Issue	Date of Issue

Certificate Expiry Date: 05-26-2024

MicroVention Inc., 35 Enterprise, Aliso Viejo, California, 92656, USA
Tel : 714-247-8000 – Fax : 714-247-8005 www.microvention.com

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

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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 4 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 şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

V-Grip Detachment Controller	**VG501**
Azur Detachment Controller	**45-4001**
WEB Detachment Controller	**WDC-1**
	WDC-2

Se anexează următoarele acte:
1) Declarație de Conformitate, nr. RF 20-0014 Rev. B din 08.08.2022;
2) Certificarte CE no. 411133 MR2
3) 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	