Headway 156cm Microcatheter

Now with Headway Duo! microcatheter Technology

Hybrid braid/coil construction to improve stent delivery experience

Headway 21 Microcatheter 156cm

Headway 27 Microcatheter 156cm

Hybrid Braid & Coil Design

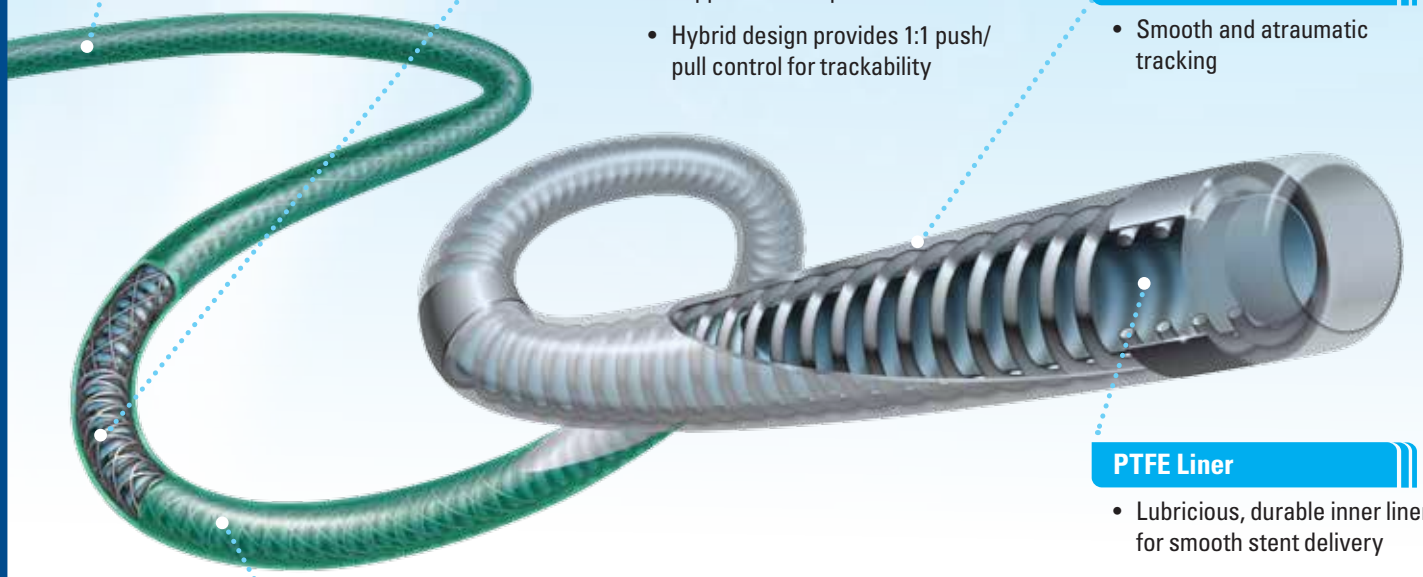
- Coil reinforcement provides lumen integrity, bending flexibility and excellent shape retention
- Proximal variable braid reinforcement provides support and torque control
- Hybrid design provides 1:1 push/pull control for trackability

Stretch Resistant Shaft

- For stability and prevention of catheter body twisting

Soft Distal Shaft

- Smooth and atraumatic tracking



PTFE Liner

- Lubricious, durable inner liner for smooth stent delivery

Lubricious Hydrophilic Coating

- Reduced friction during navigation in tortuous anatomy and during lengthy procedures

MicroVention TERUMO

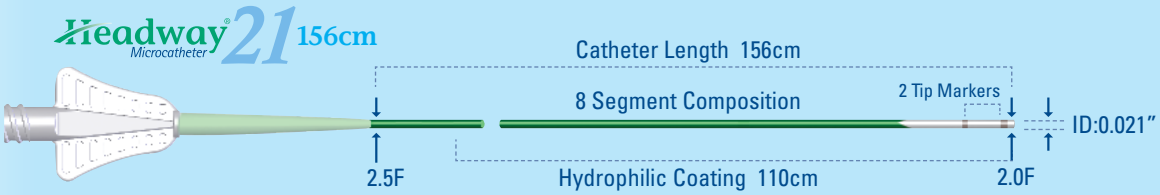
SPECIFICATIONS

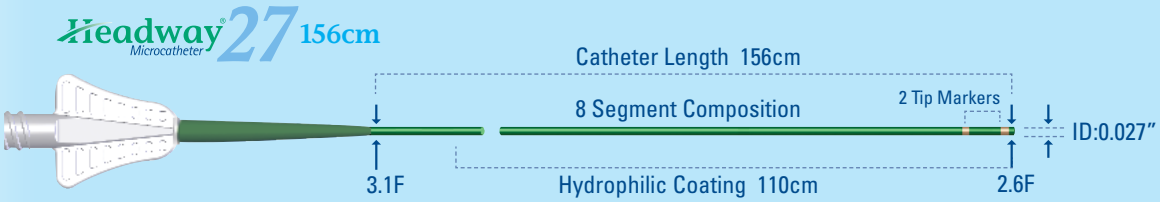
Headway® 21 & 27 (156cm) Microcatheter

Microcatheter with Hydrophilic Coating

Packed 1 per box; includes shaping mandrel and introducer sheath

Product Name	Description	Product Code	ID (inches)	Tip Shape	Usable Length (cm)	OD Prox./Distal (French)	Tip Markers
Headway 21 156cm	Straight	MC212156S	0.021	STR	156	2.5 / 2.0	2
Headway 27 156cm	Straight	MC272156S	0.027	STR	156	3.1 / 2.6	2





Headway Duo microcatheter

Technology

Hybrid Braid/Coil Design

Features

- Proximal column strength for stability and torqueability
- 156cm working length with distal flexible transitions
- Resistance to kinking and ovalization
- Resistance to stretching
- Resistance to twisting

Benefits

✓Facilitate access to the lesion

✓Smooth device trackability

✓Controlled device delivery

MicroVention TERUMO

INDICATIONS FOR USE

The Headway Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.

CE 0297

MicroVention, Inc.
Worldwide Headquarters PH +1.714.247.8000
1311 Valencia Avenue
Tustin, CA 92780 USA
MicroVention UK Limited PH +44 (0) 191 258 6777
MicroVention Europe, S.A.R.L. PH +33 (1) 39 21 77 46
MicroVention Deutschland GmbH PH +49 211 210 798-0
Web **microvention.com**

CERTIFICATE

This is to certify that the company

MicroVention, Inc.

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

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	411133 MP2016
Certificate unique ID	170758666
Effective date	2019-11-17
Expiry date	2022-11-16
Frankfurt am Main	2019-11-17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

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

410.90.en Version 1.0

Annex to certificate
Certificate registration No.: 411133 MP2016
Certificate unique ID: 170758666
Effective date: 2019-11-17

MicroVention, Inc.

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

Location	Scope
MicroVention, Inc. **Production Site** 35 Enterprise Aliso Viejo, CA, 92656 United States of America	Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.
MicroVention, Inc. **Production Site** 1311 Valencia Ave. Tustin, CA, 92780 United States of America	Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.
MicroVention Costa Rica, S.R.L. **Production Site** Zona Franca Coyol Alajuela Costa Rica	Manufacturing of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheter, Guiding and Aspiration Catheters, and Microcatheters), Stents, Clot and Foreign Body Retrieval Devices, Embolic Protection System, and Aspiration Devices.

EC DECLARATION OF CONFORMITY

FD08-011 / W

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: 435827 MRA (Section 4)
Full Quality Assurance: 411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
Headway 17 Advanced Soft Microcatheter	MC172150S	III – Annex 9, rule 7	2018-12-19	10691
Headway 17 Advanced Microcatheter	MC172150STX, MC17215045X, MC17215090X, MC172150AX, MC172150BX, MC172150CX, MC172150DX, MC172150WX, MC172150JX, MC172150SX			
Headway 21 Microcatheter	MC212150S, MC212156S			
Headway 27 Microcatheter	MC272150S, MC272156S			
Headway Duo	MC162156S, MC162167S			
Wedge Microcatheter	MCWED21160	III – Annex 9, rule 8	2018-12-19	10691

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:
MicroVention Costa Rica
Zona Franca Coyol
Alajuela, Costa Rica

Intended Use:
The Headway Microcatheter (Headway 17 Advanced Soft, Headway 17 Advanced, 21 & 27) is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.

The Headway Duo Microcatheter is intended for general intravascular use, including the peripheral and coronary vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials.

The Wedge Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and to assist in the delivery of interventional devices, such as the SOFIA 6F Catheter, in the neurovasculature.

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.

Salvadore Palomares
Director, Regulatory Affairs
MicroVention, Inc.

Tustin, CA 92780, USA
Place of Issue

19-DEC-2018
Date of Issue

Expiry Date: 2022-12-19

MicroVention 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, Detachment Controller Units, Syringe Kits, Stents, Clot and Foreign Body Retrieval Devices, Intravascular Access Devices (Occlusion Balloon Catheters, Micro Catheters, Guidewires), Liquid Embolic System, EPS Embolic Protection System, Microspheres and Aneurysm Embolization Device 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	170711729
Effective date	2018-06-11
Expiry date	2022-11-02
Frankfurt am Main	2018-06-11

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.

Prepared for Romania

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170711729
Effective date: 2018-06-11

MicroVention, Inc.

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

Production Sites:

1.
MicroVention, Inc.
1311 Valencia Ave.
Tustin, CA 92780
United States of America

2.
MicroVention, Inc.
35 Enterprise,
Aliso Viejo, CA 92656
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: 170711729
Effective date: 2018-06-11

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolization Prothese	V-Trak® Detachable Embolization Coils System	MicroPlex® Platinum Detachable Embolization Coils - Helical IStandard Helical-Reg. and Soft 10 & 18, - HyperSoft® 10 & 3D - Complex 10 & 18 - Compass 10 & 18, - COSMOS® 10 & 18 - VFC™	III	1,2,3
		HydroCoil® Platinum/Hydrogel Detachable Embolization Coils - HydroCoil® 10 & 14 & 18, - HydroSoft® 10 - HydroFill® - HydroFrame® 10 & 18 - HydroSoft 3D	III	1,2,3
	AZUR® Peripheral Coil System	AZUR® HydroCoil Detachable Embolization Coils 18 & 35 AZUR® HydroCoil Pushable Embolization Coils 18 & 35 AZUR® Framing Detachable Coils 18 & 35 AZUR® Injectable Coil System 18 & 35 AZUR Detachable 18 AZUR PURE Pushable Coil System 18 & 35 AZUR CX Detachable 18 & 35	IIb	1,2,3
Detachment Controller Units		V-Grip® Detachment Controller	IIa	1
		V-Grip® PLUS Detachment Controller	IIa	1
		WEB Detachment Controller	IIa	1
		AZUR® Detachment Controller	IIa	1

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170711729
Effective date: 2018-06-11

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Intravascular Access Devices		Traxcess® 14 Guidewire	III	1
		Traxcess® 14 EX Guidewire		
		Traxcess® 14 SELECT Guidewire		
		Traxcess® 7 Mini Guidewire		
		Traxcess® 7 Mini XSoft Guidewire		
		Traxcess® Docking Wire	IIa	1
Catheters		Chaperon® Guiding Catheter System	III	1
		Headway® 17 Advanced Soft Microcatheter		1,3
		Headway® 17 Advanced Microcatheter		1,3
		Headway® 21 Microcatheter		1,3
		Headway® 27 Microcatheter		1,3
		Headway Duo Microcatheter		1,3
		Scepter C™ Occlusion Balloon Catheter		1,3
		Scepter XC™ Occlusion Balloon Catheter		1,3
		SOFIA Distal Access Catheter		1,2,3
		SOFIA Select Catheter		1,2,3
		SOFIA PLUS Catheter		1,2,3
		SOFIA Flow PLUS Catheter		1,2,3
		SOFIA Guiding Catheter		1,2,3
		SOFIA Flow Catheter		1,2,3
		KANSHAS Drug Coated Balloon		1
		VIA I17 Microcatheter		1
		VIA I21 Microcatheter		
		VIA I27 Microcatheter		
		VIA I33 Microcatheter		
		Wedge Microcatheter		1

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170711729
Effective date: 2018-06-11

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		
		FRED® Flow Re-Direction Endoluminal Device	III	1,3
		FRED Jr.® Flow Re-Direction Endoluminal Device		1,3
		CASPER IRX Carotid Artery Stent System		1,3
		Roadsaver Carotid Artery Stent System		1,3
Peripheral vascular stent system		CASPER Peripheral Vascular Stent System	IIb	1,3
		RENZAN Peripheral Vascular Stent System	IIb	1,3
Clot Retriever		ERIC™ Retrieval Device	III	1,2
Liquid Embolic System		PHIL™ Liquid Embolic System	III	1
Microspheres		HydroPearl Microspheres	IIb	1
		LifePearl Microspheres	III	1,2
Embolic Protection Device (EPS)		Empro Embolic Protection System	III	1,2,3
		Nanoparasol Embolic Protection System		
Aneurysm Embolization Device		WEB IAneurysm Embolization System	III	1

Headway Duo microcatheter

Innovative Catheter Technology

Unique braid/coil construction for the lowest profile of any 0.014"/ 0.012" guidewire compatible catheter

Headway® Duo Microcatheter

Microcatheter with Hydrophilic Coating

1 per box; includes shaping mandrel and introducer sheath

Product Name	Product Code	ID Body/Tip (inches)	Tip Shape	Usable Length (cm)	Flexible Distal Length (cm)	OD Prox./Dist. (French)	Dead Space	Tip Markers
Headway Duo, 156cm	MC162156S	0.0165 / 0.0165	STR	156	9	2.1 / 1.6	0.34 ml	2
Headway Duo, 167cm	MC162167S	0.0165 / 0.013	STR	167	9	2.1 / 1.3	0.35 ml	1

Features

Benefits

Hybrid Braid/Coil Design

Tight pitch coil provides lumen integrity and bending flexibility
Proximal braid provides firmness and a torqueable catheter body
Resists kinking and ovalization

Small OD, Large ID

156cm Headway® Duo microcatheter compatible with coils and ≤0.014" OD guidewires
0.0165" body ID microcatheter with low profile distal tip

167cm Headway® Duo microcatheter compatible with ≤0.014"/≤0.012" (proximal/distal OD) guidewires
0.0165" body ID microcather with 0.013" ID distal tapered tip

Superior Trackability

True 1:1 push/pull while tracking through tortuous anatomy

Liquid Embolic Compatibility

Compatible with PHIL™ Liquid Embolic, Onyx™ Liquid Embolic, nBCA and DMSO
High burst strength (700 psi)
Long length allows distal lesion access

Soft Distal Tip

Smooth, atraumatic tracking
Excellent tip "painting" ability

MicroVention TERUMO

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MicroVention UK Limited PH +44 (0) 191 258 6777
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MicroVention Deutschland GmbH PH +49 211 210 798-0
Web **microvention.com**

CE 0297

MM268(I) Rev.C 8/14

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

01.01.2020

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 DISPOZIIVE 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:

- Portofoliu neurovascular **MicroVention**:

Microghiduri neurovasculare: TRAXCESS 14, TRAXCESS 14EX

Microcatetere neurovasculare: HEADWAY DUO, HEADWAY 17, HEADWAY 21, HEADWAY 27

Catetere de ghidaj: CHAPERON

Catetere de acces distal cu aspiratie: SOFIA

Balon cu dublu-lumen: SCEPTER C, SCEPTER XC

Stent intraluminal: LVIS, LVIS Jr.

Stent revascularizare: FRED, FRED Jr.

Stent recuperare trombi: ERIC

Spirale intracraniene din platina: VFC, MICROPLEX: HYPER SOFT, HELICAL, COSMOS, HYPER SOFT 3D

Spirale intracraniene din platina acoperite cu hydrogel: HYDROFRAME, HYDROFILL, HYDROSOFT

Dispozitiv intrasaccular de embolizare: WEB

Microcateter compatibil cu dispozitiv intrasaccular de embolizare: VIA

Detasator pentru dispozitiv intrasaccular de embolizare

- Portofoliu **Asahi Intecc** – INR & IVR:

Microghiduri neurovasculare: ASAHAI CHIKAI

Catetere de ghidaj neurovascular: FUBUKI, FUBUKI 043

Ghiduri periferice IVR: Meister 16, Asahi Chikai V

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 producatorii MICROVENTION si respectiv ASAHI INTECC.

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.

Societatea Comerciala TECMED S.R.L. Romania

TECMED S.R.L.
IEŞIRE NR. 312
Ziua 01 Luna 01 Anul 2020

TECMED SRL

Gheorghe Diaconu,
Administrator

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 Comercială TECMED S.R.L. România

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