

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

Sediu 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

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) LVIS	212928-XCAS	LEV3018
212517-CAS	212931-XCAS	LEV3024
212525-CAS	213015-XCAS	LEV3028
213517-CAS	213025-XCAS	LEV3032
213522-CAS	213041-XCAS	LEV3517
212912-CAS	214035-XCAS	LEV3522
212917-CAS	214049-XCAS	LEV3528
212922-CAS		LEV3534
212928-CAS	3) LVIS Jr	LEV4013
212931-CAS	172010-CASJ	LEV4018
214017-CAS	172014-CASJ	LEV4021
214022-CAS	172020-CASJ	LEV4027
214028-CAS	172032-CASJ	LEV4031
214031-CAS	172516-CASJ	6) LVIS EVO X
213015-CAS	172524-CASJ	XLEV2512
213025-CAS	172530-CASJ	XLEV2517
213041-CAS	172537-CASJ	XLEV2522
214518-CAS	4) LVIS Jr X	XLEV2527
214523-CAS	172010-XCASJ	XLEV3018
214532-CAS	172014-XCASJ	XLEV3024
214035-CAS	172020-XCASJ	XLEV3028
214049-CAS	172032-XCASJ	XLEV3032
215530-CAS	172516-XCASJ	XLEV3517
215533-CAS	172524-XCASJ	XLEV3522
	172530-XCASJ	XLEV3528
	172537-XCASJ	XLEV3534
2) LVIS X	5) LVIS EVO	XLEV4013
212517-XCAS	LEV2512	XLEV4018
212525-XCAS	LEV2517	XLEV4021
212912-XCAS	LEV2522	XLEV4027
212917-XCAS	LEV2527	XLEV4031
212922-XCAS		

Se anexează următoarele acte:

- 1) Declarație de Conformitate, din 23.06.2020;
- 2) Certificate CE no. 411133MR2 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

Semnătura _____

Grabazei Alexandru, director general.

Data 27.09.2023

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. 6 din 27.09.2023

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) LVIS	212928-XCAS	LEV3018
212517-CAS	212931-XCAS	LEV3024
212525-CAS	213015-XCAS	LEV3028
213517-CAS	213025-XCAS	LEV3032
213522-CAS	213041-XCAS	LEV3517
212912-CAS	214035-XCAS	LEV3522
212917-CAS	214049-XCAS	LEV3528
212922-CAS		LEV3534
212928-CAS	3) LVIS Jr	LEV4013
212931-CAS	172010-CASJ	LEV4018
214017-CAS	172014-CASJ	LEV4021
214022-CAS	172020-CASJ	LEV4027
214028-CAS	172032-CASJ	LEV4031
214031-CAS	172516-CASJ	6) LVIS EVO X
213015-CAS	172524-CASJ	XLEV2512
213025-CAS	172530-CASJ	XLEV2517
213041-CAS	172537-CASJ	XLEV2522
214518-CAS	4) LVIS Jr X	XLEV2527
214523-CAS	172010-XCASJ	XLEV3018
214532-CAS	172014-XCASJ	XLEV3024
214035-CAS	172020-XCASJ	XLEV3028
214049-CAS	172032-XCASJ	XLEV3032
215530-CAS	172516-XCASJ	XLEV3517
215533-CAS	172524-XCASJ	XLEV3522
	172530-XCASJ	XLEV3528
	172537-XCASJ	XLEV3534
2) LVIS X	5) LVIS EVO	XLEV4013
212517-XCAS	LEV2512	XLEV4018
212525-XCAS	LEV2517	XLEV4021
212912-XCAS	LEV2522	XLEV4027
212917-XCAS	LEV2527	XLEV4031
212922-XCAS		

Se anexează următoarele acte:

- 1) Declarație de Conformitate, nr. RF 19-0044 Rev. C din 23.06.2020;
- 2) Certificarte CE no. 487703 MR2 din 29.04.2021.
- 3) Certificarte CE Design no. 490690 MRA din 05.05.2020.
- 4) Actul prin care producătorul își desemnează reprezentantul

Data 27.09.2023

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	

EC DECLARATION OF CONFORMITY

RF 19-0044 Rev. C

DC Number: DC20-03704

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 ☒ (Annex II.4) 490690 MRA Certificate Number	EC Full Quality Assurance Certificate ☒ (Annex II.3) 487703 MR2 Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
LVIST™ Intraluminal Support Device LVIST™ Jr. Intraluminal Support Device LVIST™ EVO™ Intraluminal Support Device LVIST™ XT™ Intraluminal Support Device LVIST™ Jr. XT™ Intraluminal Support Device LVIST™ EVO™ XT™ Intraluminal Support Device	See attached list	Class III – Annex IX, Rule 8 Subclause 2	46352

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 Costa Rica, S.R.L. Zona Franca Coyol Alajuela, Costa Rica MicroVention, Inc. 35 Enterprise Aliso Viejo, California 92656 USA	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297

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.

I. Kulinets

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

Saint-Germain-en-Laye,
France
Place of Issue

6/23/2020
Date of Issue

Certificate Expiry Date: 26 May 2024

LVIS Intraluminal Support Device Product Family

EC DECLARATION OF CONFORMITY

LVIS Model Numbers			
212517-CAS 212525-CAS 213517-CAS 213522-CAS	212912-CAS 212917-CAS 212922-CAS 212928-CAS 212931-CAS 214012-CAS 214017-CAS 214022-CAS 214028-CAS 214031-CAS	213015-CAS 213025-CAS 213041-CAS 214518-CAS 214523-CAS 214532-CAS	214035-CAS 214049-CAS 215530-CAS 215533-CAS
LVIS X Model Numbers			
212517-XCAS 212525-XCAS	212912-XCAS 212917-XCAS 212922-XCAS 212928-XCAS 212931-XCAS	213015-XCAS 213025-XCAS 213041-XCAS	214035-XCAS 214049-XCAS
LVIS Jr Model Numbers			
172010-CASJ 172014-CASJ 172020-CASJ 172032-CASJ		172516-CASJ 172524-CASJ 172530-CASJ 172537-CASJ	
LVIS Jr X Model Numbers			
172010-XCASJ 172014-XCASJ 172020-XCASJ 172032-XCASJ		172516-XCASJ 172524-XCASJ 172530-XCASJ 172537-XCASJ	
LVIS EVO Model Numbers			
LEV2512 LEV2517 LEV2522 LEV2527	LEV3018 LEV3024 LEV3028 LEV3032	LEV3517 LEV3522 LEV3528 LEV3534	LEV4013 LEV4018 LEV4021 LEV4027 LEV4031
LVIS EVO X Model Numbers			
XLEV2512 XLEV2517 XLEV2522 XLEV2527	XLEV3018 XLEV3024 XLEV3028 XLEV3032	XLEV3517 XLEV3522 XLEV3528 XLEV3534	XLEV4013 XLEV4018 XLEV4021 XLEV4027 XLEV4031



EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvor
78100 Saint-Germain-en-Laye
France

that the design of the following device(s)

Low-Profile Visualized Intraluminal Support Device in the variants as listed in Annex

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. 487703 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: LVIS STED_Final Version_Amended July 10 2019.docx
dated 2019-07-10
ST19-005 Revision B_LVIS STED_Mar2020_Clean Copy.docx
dated 2020-03-16

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

Examination report: 411_18e_Report_TFR_LVIS_LVIS Jr. docx dated 2019-07-22
411133_Report_TFR_LVIS_LVISJr_V2.docx dated 2020-05-05

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

Certificate registration no. 490690 MRA

Certificate unique ID 170769614

Effective date 2020-05-05

Expiry date 2024-05-26

Frankfurt am Main 2020-05-05

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.: 490690 MRA

Certificate unique ID: 170769614

Effective date: 2020-05-02

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvier
78100 Saint-Germain-en-Laye
France

Low-Profile Visualized Intraluminal Support Device

LVIS™ Intraluminal Support Device
LVIS™ Jr. Intraluminal Support Device
LVIS™ EVO™ Intraluminal Support Device
LVIS™ X™ Intraluminal Support Device
LVIS™ Jr. X™ Intraluminal Support Device
LVIS™ EVO™ X™ Intraluminal Support Device



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvair
78100 Saint-Germain-en-Laye
France

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 and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Catheters, Embolic Protection System, Aneurysm Embolization Devices and Microspheres 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.	487703 MR2
Certificate unique ID	170776103
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

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Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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Annex to certificate

Certificate registration No.: 487703 MR2

Certificate unique ID: 170776103

Effective date: 2021-04-29

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvour
78100 Saint-Germain-en-Laye
France

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.: 487703 MR2

Certificate unique ID: 170776103

Effective date: 2021-04-29

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvor
78100 Saint-Germain-en-Laye
France

Device Groups:	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 Devices	III	1,2,3
	FRED Jr.™ Flow Re-Direction Endoluminal Devices		
	FRED X™ Flow Re-Direction Endoluminal Devices		
	FRED OMEGA™ Flow Re-Direction Endoluminal Devices		
	CASPER™ RX Carotid Artery Stent System	III	1,2,3
	Roadsaver™ Carotid Artery Stent System	III	1,2,3
Peripheral Vascular Stent System	CASPER™ Peripheral Vascular Stent System	IIb	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
Catheter	SOFIA™ Distal Access Catheter	III	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
	SOFIA® EX Catheter		1,2,3
	KANSHAS Drug Coated Balloon		1



Annex to certificate

Certificate registration No.: 487703 MR2

Certificate unique ID: 170776103

Effective date: 2021-04-29

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvair
78100 Saint-Germain-en-Laye
France

Device Groups:	Devices:	Risk Class	Production Site
Microspheres	HydroPearl Microspheres	Iib	1,2
	LifePearl Microspheres	III	1,2
	BioPearl® Microspheres	III	1,2
Embolic Protection Device (EPS)	Empro Embolic Protection System Nanoparasol Embolic Protection System	III	1,2,3
Aneurysm Embolization Device	WEB™ Aneurysm Embolization System	III	1,2
Detachment Controller Units	WEB Detachment Controller	Ila	1,2
Aspiration Devices	Aspiration Tubing Kit	Is	2
	Aspiration Syringe Kit	Is	2
Catheters	Peripheral Vascular Catheter	Ila	1,2



EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvor
78100 Saint-Germain-en-Laye
France

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Effective date: 2020-05-02

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvier
78100 Saint-Germain-en-Laye
France

Low-Profile Visualized Intraluminal Support Device

LVIS™ Intraluminal Support Device
LVIS™ Jr. Intraluminal Support Device
LVIS™ EVO™ Intraluminal Support Device
LVIS™ X™ Intraluminal Support Device
LVIS™ Jr. X™ Intraluminal Support Device
LVIS™ EVO™ X™ Intraluminal Support Device