EC DECLARATION OF CONFORMITY

RF 19-0097 Rev.B
DC Number: 20-05340

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) 487703 MRA **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 487703 MR2 **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
SOFIA® Distal Access Catheter	DA5115ST, DA5125ST, DA6115ST	III – Annex 9, rule 7	58173 (Thrombectomy catheter)
SOFIA® PLUS Catheter	AC6115ST, AC6125ST, AC6131ST, DA6125ST, DA6131ST, DA6135ST		58173 (Thrombectomy catheter)
SOFIA® Flow PLUS Catheter	DA6125ST, DA6131ST		58173 (Thrombectomy catheter)
SOFIA® Flow Catheter	DA5115ST, DA5125ST, AC5115ST, AC5125ST		58173 (Thrombectomy catheter)
SOFIA® EX Catheter	ISC5105ST, ISC5115ST		17846 (Vascular guide catheter, Single Use)

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

EC DECLARATION OF CONFORMITY

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:
Signer Name: Irina Kulinets
Signing Reason: I approve this document
Signing Time: 11/19/2020 | 6:28:42 PM PST
F47F956B62B5424CBF023EA37BA8F01F

Irina Kulinets Sr. Vice President, Regulatory Affairs, Quality, Clinical Research MicroVention Europe SARL	Saint-Germain-en-Laye, France	11/19/2020
	Place of Issue	Date of Issue

Certificate Expiry Date: 2024-05-26

MicroVention Europe SARL au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 4646Z
Siège Social : 30 bis, rue du Vieil Abreuvoir – 78100 Saint-Germain-en-Laye
Etablissement Secondaire (pour toutes correspondances et livraisons) 20 Quater rue Schnapper – 78100 Saint-Germain-en-Laye
Tél. : +33 (0)1 39 21 77 46 – Fax : +33 (0)1 39 21 16 01 - E-mail : contact-europe@microvention.com

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
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

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.: 487703 MR2
Certificate unique ID: 170776103
Effective date: 2021-04-29

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
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 Abreuvoir
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 FRED Jr. ™ Flow Re-Direction Endoluminal Devices FRED X™ Flow Re-Direction Endoluminal Devices 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	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 Abreuvoir
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	III	1,2,3
	Nanoparasol Embolic Protection System		
Aneurysm Embolization Device	WEB™ Aneurysm Embolization System	III	1,2
Detachment Controller Units	WEB Detachment Controller	IIa	1,2
Aspiration Devices	Aspiration Tubing Kit	Is	2
	Aspiration Syringe Kit	Is	2
Catheters	Peripheral Vascular Catheter	IIa	1,2

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. 2 din 11.07.2023

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:

1) **SOFIA® Distal Access Catheter**
DA5115ST, DA5125ST, DA6115ST

2) **SOFIA® PLUS Catheter**
AC6115ST, AC6125ST, AC6131ST, DA6125ST, DA6131ST, DA6135ST

3) **SOFIA® Flow PLUS Catheter**
DA6125ST, DA6131ST

4) **SOFIA® Flow Catheter**
DA5115ST, DA5125ST, AC5115ST, AC5125ST

5) **SOFIA® EX Catheter**
ISC5105ST, ISC5115ST

Se anexează următoarele acte:
1) Declarație de Conformitate, nr. RF 19-0097 Rev.B din 11.19.2020;
2) Certificarte CE Full no. 487703 MR2 din 29.04.2021.
3) Certificarte CE Design no. 487703 MRA din 29.08.2019.
4) Actul prin care producătorul își desemnează reprezentantul

Data 11.07.2023 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	

str. Gheorghe Bratianu nr. 30, sector 1
011413, Bucuresti, Romania
tel/fax 021 - 211.48.49, 021 – 212.37.38
email: office@tecmed.ro

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 promoze 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.

Societatea Comercială TECMED S.R.L. România

.....
Gheorghe Diaconu,

ADMINISTATOR – Director General
SC. TECMED SRL

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 Abreuvoir
78100 Saint-Germain-en-Laye
France

that the design of the following device(s)

SOFIA® Distal Access Catheter
SOFIA® Select Catheter
SOFIA® PLUS Catheter
SOFIA® Flow PLUS Catheter
SOFIA® Guiding Catheter
SOFIA® Flow Catheter
SOFIA® EX Catheter

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: SOFIA STED Executive Summary dated 2019-06-28

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

Examination report: 411_18e_Report_TFR_SOFIA_R2019_V1 dated 2019-08-29

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

Certificate registration no.	487703 MRA
Certificate unique ID	170750277
Effective date	2019-08-29
Expiry date	2024-05-26
Frankfurt am Main	2019-08-29

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.

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
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

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.: 487703 MR2
Certificate unique ID: 170776103
Effective date: 2021-04-29

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
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 Abreuvoir
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 FRED Jr. ™ Flow Re-Direction Endoluminal Devices FRED X™ Flow Re-Direction Endoluminal Devices 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	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 Abreuvoir
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	III	1,2,3
	Nanoparasol Embolic Protection System		
Aneurysm Embolization Device	WEB™ Aneurysm Embolization System	III	1,2
Detachment Controller Units	WEB Detachment Controller	IIa	1,2
Aspiration Devices	Aspiration Tubing Kit	Is	2
	Aspiration Syringe Kit	Is	2
Catheters	Peripheral Vascular Catheter	IIa	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 Abreuvoir
78100 Saint-Germain-en-Laye
France

that the design of the following device(s)

SOFIA® Distal Access Catheter
SOFIA® Select Catheter
SOFIA® PLUS Catheter
SOFIA® Flow PLUS Catheter
SOFIA® Guiding Catheter
SOFIA® Flow Catheter
SOFIA® EX Catheter

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: SOFIA STED Executive Summary dated 2019-06-28

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

Examination report: 411_18e_Report_TFR_SOFIA_R2019_V1 dated 2019-08-29

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

Certificate registration no.	487703 MRA
Certificate unique ID	170750277
Effective date	2019-08-29
Expiry date	2024-05-26
Frankfurt am Main	2019-08-29

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.

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:

1) **SOFIA® Distal Access Catheter**
DA5115ST, DA5125ST, DA6115ST

2) **SOFIA® PLUS Catheter**
AC6115ST, AC6125ST, AC6131ST, DA6125ST, DA6131ST, DA6135ST

3) **SOFIA® Flow PLUS Catheter**
DA6125ST, DA6131ST

4) **SOFIA® Flow Catheter**
DA5115ST, DA5125ST, AC5115ST, AC5125ST

5) **SOFIA® EX Catheter**
ISC5105ST, ISC5115ST

Se anexează următoarele acte:
1) Declarație de Conformitate, nr. RF 19-0097 Rev.B din 11.19.2020;
2) Certificarte CE Full no. 487703 MR2 din 29.04.2021.
3) Certificarte CE Design no. 487703 MRA din 29.08.2019.
4) Actul prin care producătorul își desemnează reprezentantul

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Grabazei Alexandru, director general. *Data 11.07.2023*