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)

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

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: FRED-FRED Jr STED.docx dated 2019-02-22
FRED-FRED Jr-FRED X STED_29Jan2020_Clean Copy.docx dated 2020-01-29
ST012 Rev B FRED Product family STED.pdf dated 2021-04-10

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

Examination report: 411_18e_Report_TFR_Sample_Version 6.docx dated 2019-06-24
411_18e_Report_TFR_FRED Change FRED X 2020.docx dated 2020-03-23
411_18e_Report_TFR_FRED Change FRED OMEGA 2021.docx dated 2021-04-29

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

Certificate registration no.	502357 MRA
Certificate unique ID	170775718
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.

Digitally signed by Grabazei Alexandru
Date: 2021.04.30 15:42:07 EEST
Reason: MoldSign Signature
Location: Moldova

EC DECLARATION OF CONFORMITY

RF 19-0025 Rev. B
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) 502357 MRA **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 487703 MR2 **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
FRED® Flow Re-Direction Endoluminal Device FRED® Jr. Flow Re-Direction Endoluminal Device FRED® X™ Flow Re-Direction Endoluminal 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.

J. 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

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 DECLARATION OF CONFORMITY

FRED, FRED Jr and FRED X Flow Re-Direction Endoluminal Device
Model Numbers

FRED			
FRED3507	FRED4007	FRED4508	FRED5009
FRED3509	FRED4009	FRED4511	FRED5011
FRED3511	FRED4012	FRED4513	FRED5014
FRED3513	FRED4014	FRED4518	FRED5019
FRED3516	FRED4017	FRED4524	FRED5026
FRED3524	FRED4026	FRED4528	FRED5029
FRED3536	FRED4038	FRED4539	FRED5514
			FRED5519
			FRED5526
FRED Jr.			
FREDJR2508	FREDJR2518	FREDJR3009	FREDJR3019
FREDJR2509	FREDJR2519	FREDJR3010	FREDJR3020
FREDJR2510	FREDJR2520	FREDJR3011	FREDJR3021
FREDJR2511	FREDJR2521	FREDJR3012	FREDJR3022
FREDJR2512	FREDJR2522	FREDJR3013	FREDJR3023
FREDJR2513	FREDJR2523	FREDJR3014	FREDJR3024
FREDJR2514	FREDJR2524	FREDJR3015	FREDJR3025
FREDJR2515	FREDJR2525	FREDJR3016	FREDJR3026
FREDJR2516	FREDJR2526	FREDJR3017	FREDJR3027
FREDJR2517		FREDJR3018	
FRED X			
XFRED3507	XFRED4007	XFRED4508	XFRED5009
XFRED3509	XFRED4009	XFRED4511	XFRED5011
XFRED3511	XFRED4012	XFRED4513	XFRED5014
XFRED3513	XFRED4014	XFRED4518	XFRED5019
XFRED3516	XFRED4017	XFRED4524	XFRED5026
XFRED3524	XFRED4026	XFRED4528	XFRED5029
XFRED3536	XFRED4038	XFRED4539	XFRED5514
			XFRED5519
			XFRED5526
XFRED2508	XFRED2518	XFRED3009	XFRED3019
XFRED2509	XFRED2519	XFRED3010	XFRED3020
XFRED2510	XFRED2520	XFRED3011	XFRED3021
XFRED2511	XFRED2521	XFRED3012	XFRED3022
XFRED2512	XFRED2522	XFRED3013	XFRED3023
XFRED2513	XFRED2523	XFRED3014	XFRED3024
XFRED2514	XFRED2524	XFRED3015	XFRED3025
XFRED2515	XFRED2525	XFRED3016	XFRED3026
XFRED2516	XFRED2526	XFRED3017	XFRED3027
XFRED2517		XFRED3018	

MicroVention Europe SARL au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 4646Z
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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
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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. 1 din 13.10.2023

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:

1) FRED
FRED3507 FRED3509 FRED35l 1 FRED3513 FRED3516 FRED3524 FRED3536 FRED4007 FRED4009 FRED40l2 FRED40l4 FRED4017 FRED4026 FRED4038 FRED4508FRED4511 FRED4513 FRED4518 FRED4524 FRED4528 FRED4539 FRED5009FRED5011 FRED5014 FRED5019 FRED5026 FRED5029 FRED5514 FRED5519 FRED5526

2) FRED Jr.
FREDJR2508 FREDJR2509 FREDJR2510 FREDJR2511 FREDJR2512 FREDJR2513 FREDJR2514 FREDJR2515 FREDJR2516 FREDJR2517 FREDJR2518 FREDJR2519 FREDJR2520 FREDJR2521 FREDJR2522 FREDJR2523 FREDJR2524 FREDJR2525 FREDJR2526 FREDJR3009 FREDJR3010 FREDJR301 1 FREDJR30l2 FREDJR3013 FREDJR3014 FREDJR3015 FREDJR3016 FREDJR3017 FREDJR3018 FREDJR3019 FREDJR3020 FREDJR3021 FREDJR3022 FREDJR3023 FREDJR3024 FREDJR3025 FREDJR3026 FREDJR3027

3) Fred X
XFRED3507
XFRED3509 XFRED351 1 XFRED3513 XFRED3516 XFRED3524 XFRED3536 XFRED2508XFRED2509 XFRED2510 XFRED2511 XFRED2512 XFRED2513 XFRED2514 XFRED2515 XFRED2516 XFRED2517 XFRED4007XFRED4009 XFRED4012 XFRED4014 XFRED4017 XFRED4026 XFRED4038 XFRED2518 XFRED2519XFRED2520 XFRED2521 XFRED2522 XFRED2523 XFRED2524 XFRED2525 XFRED2526 XFRED4508XFRED4511 XFRED4513 XFRED4518 XFRED4524 XFRED4528 XFRED4539 XFRED3009XFRED3010 XFRED301 1 XFRED3012 XFRED3013 XFRED3014 XFRED3015 XFRED3016 XFRED30I7 XFRED3018 XFRED5009 XFRED5011 XFRED5014 XFRED5019 XFRED5026 XFRED5029 XFREDSS 14 XFRED5519 XFRED5526 XFRED3019 XFRED3020XFRED3021 XFRED3022 XFRED3023 XFRED3024 XFRED3025 XFRED3026 XFRED3027

Se anexează următoarele acte:
1) Declarație de Conformitate, nr. RF19-0025 Rev. B din 09.09.2022;
2) Certificarte CE no. 487703 MR2
3) EC Design Examination Certificate no. 502357 MRA
4) Actul prin care producătorul își desemnează reprezentantul

Data 13.10.2023 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	

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

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. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1) FRED

FRED3507 FRED3509 FRED35l 1 FRED3513 FRED3516 FRED3524 FRED3536 FRED4007 FRED4009 FRED40l2 FRED40l4 FRED4017 FRED4026 FRED4038 FRED4508FRED4511 FRED4513 FRED4518 FRED4524 FRED4528 FRED4539 FRED5009FRED5011 FRED5014 FRED5019 FRED5026 FRED5029 FRED5514 FRED5519 FRED5526

2) FRED Jr.

FREDJR2508 FREDJR2509 FREDJR2510 FREDJR2511 FREDJR2512 FREDJR2513 FREDJR2514 FREDJR2515 FREDJR2516 FREDJR2517 FREDJR2518 FREDJR2519 FREDJR2520 FREDJR2521 FREDJR2522 FREDJR2523 FREDJR2524 FREDJR2525 FREDJR2526 FREDJR3009 FREDJR3010 FREDJR301 1 FREDJR30l2 FREDJR3013 FREDJR3014 FREDJR3015 FREDJR3016 FREDJR3017 FREDJR3018 FREDJR3019 FREDJR3020 FREDJR3021 FREDJR3022 FREDJR3023 FREDJR3024 FREDJR3025 FREDJR3026 FREDJR3027

3) Fred X

XFRED3507
XFRED3509 XFRED351 1 XFRED3513 XFRED3516 XFRED3524 XFRED3536 XFRED2508XFRED2509 XFRED2510 XFRED2511 XFRED2512 XFRED2513 XFRED2514 XFRED2515 XFRED2516 XFRED2517 XFRED4007XFRED4009 XFRED4012 XFRED4014 XFRED4017 XFRED4026 XFRED4038 XFRED2518 XFRED2519XFRED2520 XFRED2521 XFRED2522 XFRED2523 XFRED2524 XFRED2525 XFRED2526 XFRED4508XFRED4511 XFRED4513 XFRED4518 XFRED4524 XFRED4528 XFRED4539 XFRED3009XFRED3010 XFRED301 1 XFRED3012 XFRED3013 XFRED3014 XFRED3015 XFRED3016 XFRED30I7 XFRED3018 XFRED5009 XFRED5011 XFRED5014 XFRED5019 XFRED5026 XFRED5029 XFREDSS 14 XFRED5519 XFRED5526 XFRED3019 XFRED3020XFRED3021 XFRED3022 XFRED3023 XFRED3024 XFRED3025 XFRED3026 XFRED3027

Se anexează următoarele acte:

1) Declarație de Conformitate, nr. RF19-0025 Rev. B din 09.09.2022;
2) Certificarte CE no. 487703 MR2
3) EC Design Examination Certificate no. 502357 MRA
4) Actul prin care producătorul își desemnează reprezentantul

Sunt autentice și corespund realității

Numele, prenumele şi funcţia *Semnătura* _____

Grabazei Alexandru, director general. *Data 13.10.2023*