EC DECLARATION OF CONFORMITY

RF18-0006 Rev. G
ECN Number: 22-03480

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) 535861 MRA **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 487703 MR2 **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
WEB Aneurysm Embolization System	Refer to Table 1 below	III – Annex 9, Rule 8	60940

Legal Manufacturer	Production Site(s)	Notified Body
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	MicroVention Inc. 35 Enterprise Aliso Viejo, CA 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.

DocuSigned by:
Julie Lopez-Genest
Signer Name: Julie Lopez-Genest
Signing Reason: I approve this document
Signing Time: 9/9/2022 | 9:12:23 AM PDT
DCD9583D5FC74E5DB65E1967787FBC10

Julie Lopez-Genest Sr Manager, RA & QA, EMEA MicroVention Inc.	Saint-Germain-en-Laye, France Place of Issue	9/9/2022 Date of Issue

Certificate Expiry Date: 2024-05-26

EC DECLARATION OF CONFORMITY

Table 1: **WEB Aneurysm Embolization System Model Numbers**

Product	Model Number(s)				
WEB Aneurysm Embolization System with 027 Delivery System	W2-8-3 W2-8-4 W2-8-5 W2-8-6 W2-8-7	W2-9-4 W2-9-5 W2-9-6 W2-9-7 W2-9-8	W2-10-5 W2-10-6 W2-10-7 W2-10-8	W2-11-6 W2-11-7 W2-11-8 W2-11-9	
WEB Aneurysm Embolization System with 027 Delivery System	W2-8-S	W2-9-S	W2-10-S	W2-11-S	
WEB Aneurysm Embolization System with 021 Delivery System	W4-4-3 W4-4.5-3 W4-4-4 W4-4.5-4	W4-5-3 W4-5.5-3 W4-5-4 W4-5.5-4 W4-5-5 W4-5.5-5	W4-6-3 W4-6.5-3 W4-6-4 W4-6.5-4 W4-6-5 W4-6.5-5 W4-6-6 W4-6.5-6	W4-7-3 W4-7-4 W4-7-5 W4-7-6 W4-7-7	
WEB Aneurysm Embolization System with 021 Delivery System	W4-4-S W4-4.5-S	W4-5-S W4-5.5-S	W4-6-S W4-6.5-S	W4-7-S	
WEB Aneurysm Embolization System with 017 Delivery System	W5-3-2 W5-3-2.5 W5-3-3 W5-3.5-2 W5-3.5-2.5 W5-3.5-3 W5-3.5-3.5 W5-4-2 W5-4-2.5 W5-4-3 W5-4-3.5 W5-4-4	W5-4.5-2 W5-4.5-2.5 W5-4.5-3 W5-4.5-3.5 W5-4.5-4 W5-4.5-4.5 W5-5-2 W5-5-2.5 W5-5-3 W5-5-3.5 W5-5-4 W5-5-4.5	W5-5-5 W5-5.5-2 W5-5.5-2.5 W5-5.5-3 W5-5.5-3.5 W5-5.5-4 W5-5.5-4.5 W5-5.5-5 W5-5.5-5.5 W5-6-2 W5-6-2.5 W5-6-3	W5-6-3.5 W5-6-4 W5-6-4.5 W5-6-5 W5-6-6 W5-6.5-2 W5-6.5-2.5 W5-6.5-3 W5-6.5-3.5 W5-6.5-4 W5-6.5-4.5	W5-6.5-5 W5-6.5-5.5 W5-6.5-6 W5-7-2 W5-7-2.5 W5-7-3 W5-7-3.5 W5-7-4 W5-7-4.5 W5-7-5 W5-7-5.5 W5-7-6
WEB Aneurysm Embolization System with 017 Delivery System	W5-4-S W5-4.5-S	W5-5-S W5-5.5-S	W5-6-S W5-6.5-S	W5-7-S	

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

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 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) **WEB Aneurysm Embolization System with 027 Delivery System**

W2-8-3
W2-8-4
W2-8-5
W2-8-6
W2-8-7
W2-9-4
W2-9-5
W2-9-6
W2-9-7
W2-9-8
W2-10-5
W2-10-6
W2-10-7
W2-10-8
W2-11-6
W2-11-7
W2-11-8
W2-11-9

2) **WEB Aneurysm Embolization System with 027 Delivery System**

W2-8-S
W2-9-S
W2-10-S
W2-11-S

3) **WEB Aneurysm Embolization System with 021 Delivery System**

W4-4-3
W4-4.5-3
W4-4-4
W4-4.5-4
W4-5-3
W4-5.5-3
W4-5-4
W4-5.5-4
W4-5-5
W4-5.5-5

W4-6-3
W4-6.5-3
W4-6-4
W4-6.5-4
W4-6-5
W4-6.5-5
W4-6-6
W4-6.5-6
W4-7-3
W4-7-4
W4-7-5
W4-7-6
W4-7-7

4) **WEB Aneurysm Embolization System with 021 Delivery System**

W4-4-S
W4-4.5-S
W4-5-S
W4-5.5-S
W4-6-S
W4-6.5-S
W4-7-S

5) **WEB Aneurysm Embolization System with 017 Delivery System**

W5-3-2
W5-3-2.5
W5-3-3
W5-3.5-2
W5-3.5-2.5
W5-3.5-3
W5-3.5-3.5
W5-4-2
W5-4-2.5
W5-4-3
W5-4-3.5
W5-4-4
W5-4.5-2
W5-4.5-2.5
W5-4.5-3
W5-4.5-3.5
W5-4.5-4
W5-4.5-4.5
W5-5-2
W5-5-2.5
W5-5-3
W5-5-3.5
W5-5-4
W5-5-4.5
W5-5-5
W5-5.5-2

W5-5.5-2.5
W5-5.5-3
W5-5.5-3.5
W5-5.5-4
W5-5.5-4.5
W5-5.5-5
W5-5.5-5.5
W5-6-2
W5-6-2.5
W5-6-3
W5-6-3.5
W5-6-4
W5-6-4.5
W5-6-5
W5-6-6
W5-6.5-2
W5-6.5-2.5
W5-6.5-3
W5-6.5-3.5
W5-6.5-4
W5-6.5-4.5
W5-6.5-5
W5-6.5-5.5
W5-6.5-6
W5-7-2
W5-7-2.5
W5-7-3
W5-7-3.5
W5-7-4
W5-7-4.5
W5-7-5
W5-7-5.5
W5-7-6

6) **WEB Aneurysm Embolization System with 017 Delivery System**

W5-4-S
W5-4.5-S
W5-5-S
W5-5.5-S
W5-6-S
W5-6.5-S
W5-7-S

Se anexează următoarele acte:

1) Declarație de Conformitate, nr. RF18-0006 Rev. G din 09.09.2022;
2) Certificarte CE no. 487703 MR2 din 29.04.2021.
3) Certificart CE-Examination no. US-MF-000016658 din 31.03.2022.
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	

EC DECLARATION OF CONFORMITY

RF18-0005 Rev. E
ECN Number: 22-03348

We, MicroVention, Inc., located in Aliso Viejo, 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) 535858 **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 411133 **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
WEB Aneurysm Embolization System	Refer to Table 1 below	III – Annex 9, Rule 8	60940

Legal Manufacturer	Production Site(s)	Notified Body	EU Representative
MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 United States of America	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 USA	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.

DocuSigned by:
Amy Smith
Signer Name: Amy Smith
Signing Reason: I approve this document
Signing Time: 8/24/2022 | 3:09:08 PM PDT
6A007ED64EB548AE8E3F9AB77A2F27F6

Aliso Viejo, CA, USA	8/24/2022
Place of Issue	Date of Issue

Amy Smith
VP, Global Regulatory Affairs
MicroVention, Inc.

Certificate Expiry Date: 2024-05-26

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

EC DECLARATION OF CONFORMITY

Table 1: **WEB Aneurysm Embolization System Model Numbers**

Product	Model Number(s)				
WEB Aneurysm Embolization System with 027 Delivery System	W2-8-3 W2-8-4 W2-8-5 W2-8-6 W2-8-7	W2-9-4 W2-9-5 W2-9-6 W2-9-7 W2-9-8	W2-10-5 W2-10-6 W2-10-7 W2-10-8	W2-11-6 W2-11-7 W2-11-8 W2-11-9	
WEB Aneurysm Embolization System with 027 Delivery System	W2-8-S	W2-9-S	W2-10-S	W2-11-S	
WEB Aneurysm Embolization System with 021 Delivery System	W4-4-3 W4-4.5-3 W4-4-4 W4-4.5-4	W4-5-3 W4-5.5-3 W4-5-4 W4-5.5-4 W4-5-5 W4-5.5-5	W4-6-3 W4-6.5-3 W4-6-4 W4-6.5-4 W4-6-5 W4-6.5-5 W4-6-6 W4-6.5-6	W4-7-3 W4-7-4 W4-7-5 W4-7-6 W4-7-7	
WEB Aneurysm Embolization System with 021 Delivery System	W4-4-S W4-4.5-S	W4-5-S W4-5.5-S	W4-6-S W4-6.5-S	W4-7-S	
WEB Aneurysm Embolization System with 017 Delivery System	W5-3-2 W5-3-2.5 W5-3-3 W5-3.5-2 W5-3.5-2.5 W5-3.5-3 W5-3.5-3.5 W5-4-2 W5-4-2.5 W5-4-3 W5-4-3.5 W5-4-4	W5-4.5-2 W5-4.5-2.5 W5-4.5-3 W5-4.5-3.5 W5-4.5-4 W5-4.5-4.5 W5-5-2 W5-5-2.5 W5-5-3 W5-5-3.5 W5-5-4 W5-5-4.5	W5-5-5 W5-5.5-2 W5-5.5-2.5 W5-5.5-3 W5-5.5-3.5 W5-5.5-4 W5-5.5-4.5 W5-5.5-5 W5-5.5-5.5 W5-6-2 W5-6-2.5 W5-6-3	W5-6-3.5 W5-6-4 W5-6-4.5 W5-6-5 W5-6-6 W5-6.5-2 W5-6.5-2.5 W5-6.5-3 W5-6.5-3.5 W5-6.5-4 W5-6.5-4.5	W5-6.5-5 W5-6.5-5.5 W5-6.5-6 W5-7-2 W5-7-2.5 W5-7-3 W5-7-3.5 W5-7-4 W5-7-4.5 W5-7-5 W5-7-5.5 W5-7-6
WEB Aneurysm Embolization System with 017 Delivery System	W5-4-S W5-4.5-S	W5-5-S W5-5.5-S	W5-6-S W5-6.5-S	W5-7-S	

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

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-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. 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) **WEB Aneurysm Embolization System with 027 Delivery System**

W2-8-3
W2-8-4
W2-8-5
W2-8-6
W2-8-7
W2-9-4
W2-9-5
W2-9-6
W2-9-7
W2-9-8
W2-10-5
W2-10-6
W2-10-7
W2-10-8
W2-11-6
W2-11-7
W2-11-8
W2-11-9

2) **WEB Aneurysm Embolization System with 027 Delivery System**

W2-8-S
W2-9-S
W2-10-S
W2-11-S

3) **WEB Aneurysm Embolization System with 021 Delivery System**

W4-4-3
W4-4.5-3
W4-4-4
W4-4.5-4
W4-5-3
W4-5.5-3

W4-5-4
W4-5.5-4
W4-5-5
W4-5.5-5
W4-6-3
W4-6.5-3
W4-6-4
W4-6.5-4
W4-6-5
W4-6.5-5
W4-6-6
W4-6.5-6
W4-7-3
W4-7-4
W4-7-5
W4-7-6
W4-7-7

4) **WEB Aneurysm Embolization System with 021 Delivery System**

W4-4-S
W4-4.5-S
W4-5-S
W4-5.5-S
W4-6-S
W4-6.5-S
W4-7-S

5) **WEB Aneurysm Embolization System with 017 Delivery System**

W5-3-2
W5-3-2.5
W5-3-3
W5-3.5-2
W5-3.5-2.5
W5-3.5-3
W5-3.5-3.5
W5-4-2
W5-4-2.5
W5-4-3
W5-4-3.5
W5-4-4
W5-4.5-2
W5-4.5-2.5
W5-4.5-3
W5-4.5-3.5
W5-4.5-4
W5-4.5-4.5
W5-5-2
W5-5-2.5
W5-5-3
W5-5-3.5

W5-5-4
W5-5-4.5
W5-5-5
W5-5.5-2
W5-5.5-2.5
W5-5.5-3
W5-5.5-3.5
W5-5.5-4
W5-5.5-4.5
W5-5.5-5
W5-5.5-5.5
W5-6-2
W5-6-2.5
W5-6-3
W5-6-3.5
W5-6-4
W5-6-4.5
W5-6-5
W5-6-6
W5-6.5-2
W5-6.5-2.5
W5-6.5-3
W5-6.5-3.5
W5-6.5-4
W5-6.5-4.5
W5-6.5-5
W5-6.5-5.5
W5-6.5-6
W5-7-2
W5-7-2.5
W5-7-3
W5-7-3.5
W5-7-4
W5-7-4.5
W5-7-5
W5-7-5.5
W5-7-6

6) **WEB Aneurysm Embolization System with 017 Delivery System**

W5-4-S
W5-4.5-S
W5-5-S
W5-5.5-S
W5-6-S
W5-6.5-S
W5-7-S

Se anexează următoarele acte:

1) Declarație de Conformitate, nr. RF18-0006 Rev. G din 09.09.2022;

2) Certificarte CE no. 487703 MR2 din 29.04.2021.
3) Certificart CE-Examination no. US-MF-000016658 din 31.03.2022.
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*