EC DECLARATION OF CONFORMITY

RF21-0041, Rev. B
ECN23-00214

Regulation: Medical Device Regulation 2017/745

Conformity Assessment Route:
Medical Device Regulation 2017/745 Annex IX Chapter I, II and III
MDR Annex IX, Art. 4 (Technical Document Assessment) 497135 MDR2017P
MDR Annex IX, Art. 3 (QMS Surveillance Assessment) 487703 MDR2017Q

Device Trade Name	Catalogue Number(s)	UDI Device Identifier	Date CE Mark Affixed
WEB Aneurysm Embolization System	Please refer to Table 1 below	Please refer to Table 1 below	2022-03-31

Basic UDI-DI: 08402732WEBTL
Device Classification-Rule: Class III, Annex VIII, Rule 8
EMDN Code: C010402020399 Embolization Devices- Other
GMDN Code: 60940 Neurovascular embolization coil
Intended Purpose: The WEB Aneurysm Embolization System is intended for the endovascular embolization of ruptured and unruptured intracranial aneurysms and other neurovascular abnormalities such as arteriovenous fistulae (AVF).
The WEB Aneurysm Embolization System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation.

Manufacturer	**Production Site(s)**
Name: MicroVention, Inc. Address: 35 Enterprise, Aliso Viejo, CA, 92656 SRN: US-MF-000016658	Name: MicroVention, Inc. Address: 35 Enterprise, Aliso Viejo, CA, 92656 Name: MicroVention, Costa Rica, S.R.L Address: Zona Franca Coyol Alajuela, Costa Rica (for delivery system sub-assembly only)
European Representative	**Notified Body**
Name: MicroVention Europe SARL Address: 30 bis, rue du Vieil Abreuvoir 78100 Saint Germain-en-Laye, France SRN: FR-MF-000004448	Name: DQS Medizinprodukte GmbH Address: D-60433 Frankfurt am Main, Germany Notified Body Number: 0297

This declaration of conformity is issued under the sole responsibility of MicroVention, Inc. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices and other relevant harmonized standards and common specifications listed in **Appendix A**. This declaration is supported by the Quality System approval to ISO 13485 issued by DQS Medizinprodukte GmbH.
All supporting documentation is retained at the premises of the manufacturer.

DocuSigned by:
Sanjay Sharma
Signer Name: Sanjay Sharma
Signing Reason: I have reviewed this document
Signing Time: 2/14/2023 | 12:44:03 PM PST
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Sanjay Sharma Director, Regulatory Affairs	Aliso Viejo, CA USA Place of Issue	2/14/2023 Date of Issue

Certificate Expiry Date: 2027-03-30

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Appendix A. Other relevant harmonized standards and common specifications

The regulations, guidance documents and harmonized standards applied to the WEB Aneurysm Embolization System are listed in the tables below.

Region	Compliance	Regulation
European Union	☒ Full ☐ Partial	Medical Device Regulations 2017/745

Standards	Compliance	Name	Edition
Quality System			
EN ISO 13485	☒ Full ☐ Partial	Medical devices - Quality management systems - Requirements for regulatory purposes	2016/AC:2016
EN ISO 14971	☒ Full ☐ Partial	Medical devices - Application of risk management to medical devices	2012
EN 62366-1	☒ Full ☐ Partial	Medical devices - Application of usability engineering to medical devices	2015/AC:2015
ISO 14644-1	☒ Full ☐ Partial	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness	2015
ISO 14644-2	☒ Full ☐ Partial	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	2015
Packaging, Labeling, and Sterilization			
BS EN 1041	☒ Full ☐ Partial	Information supplied by the manufacturer of medical devices	2008+A1:2013
EN ISO 11607-1	☒ Full ☐ Partial	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2009
EN ISO 11607-2	☒ Full ☐ Partial	Packaging for terminally sterilized medical devices - Part 2: Validation	2006

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		requirements for forming, sealing and assembly processes	
EN ISO 15223-1	☒ Full ☐ Partial	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
EN ISO 11137-1	☒ Full ☐ Partial	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2015
EN ISO 11137-2	☒ Full ☐ Partial	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	2015
ISTA 3A	☒ Full ☐ Partial	ISTA (International Safe Transit Association) Procedure 3A – Performance Tests for Packaged-Products for Parcel Delivery System 150 lbs. (70 kg) or Less	2018
Biocompatibility			
AAMI/ISO 10993-1	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2018
EN ISO 10993-3	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014
EN ISO 10993-4	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	2009
EN ISO 10993-5	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
ISO 10993-6	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2016
ISO 10993-10	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010

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EN ISO 10993-11	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2018
EN ISO 10993-12	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012
EN ISO 10993-17	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	2009
EN ISO 10993-18	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	2009
Product Specific			
ASTM F88	☒ Full ☐ Partial	Standard Test Method for Seal Strength of Flexible Barrier Materials	2015
ASTM F2063	☒ Full ☐ Partial	Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants	2018
ASTM B561	☒ Full ☐ Partial	Standard Specification for Refined Platinum	2018
ASTM A908	☒ Full ☐ Partial	Standard Specification for Stainless Steel Needle Tubing	2003
ASTM B684	☒ Full ☐ Partial	Standard Specification for Platinum-Iridium Electrical Contact Materials	2016

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Table 1: WEB Aneurysm Embolization System device configurations (MVI)						
Catalog Number	Legal MFG	Dim "A" (D)	Dim "B" (H)	IFU Number	In-House Printed Label Box & Pouch	Product Pouch Barcode & Pouch/UDI-DI
W5-3.5-2	MVI	3.5 mm	2.0 mm	IFU100150	LB12173-3502	0100840273200093
W5-3-2	MVI	3.0 mm	2.0 mm	IFU100150	LB12173-0302	0100840273200109
W5-4.5-2	MVI	4.5 mm	2.0 mm	IFU100150	LB12173-4502	0100840273200116
W5-4.5-3	MVI	4.5 mm	3.0 mm	IFU100150	LB12173-4503	0100840273200123
W5-4-2	MVI	4.0 mm	2.0 mm	IFU100150	LB12173-0402	0100840273200130
W5-4-3	MVI	4.0 mm	3.0 mm	IFU100150	LB12173-0403	0100840273200147
W5-4-S	MVI	4.0 mm	2.6 mm	IFU100150	LB12175-0426	0100840273200154
W5-5-2	MVI	5.0 mm	2.0 mm	IFU100150	LB12173-0502	0100840273200161
W5-5-3	MVI	5.0 mm	3.0 mm	IFU100150	LB12173-0503	0100840273200178
W5-5-4	MVI	5.0 mm	4.0 mm	IFU100150	LB12173-0504	0100840273200185
W5-5-S	MVI	5.0 mm	3.6 mm	IFU100150	LB12175-0536	0100840273200192
W5-6-2	MVI	6.0 mm	2.0 mm	IFU100150	LB12173-0602	0100840273209218
W5-6-3	MVI	6.0 mm	3.0 mm	IFU100150	LB12173-0603	0100840273200208
W5-6-4	MVI	6.0 mm	4.0 mm	IFU100150	LB12173-0604	0100840273200215
W5-6-5	MVI	6.0 mm	5.0 mm	IFU100150	LB12173-0605	0100840273200222
W5-6-S	MVI	6.0 mm	4.6 mm	IFU100150	LB12175-0646	0100840273200239
W5-7-2	MVI	7.0 mm	2.0 mm	IFU100150	LB12173-0702	0100840273209225
W5-7-3	MVI	7.0 mm	3.0 mm	IFU100150	LB12173-0703	0100840273200246
W5-7-4	MVI	7.0 mm	4.0 mm	IFU100150	LB12173-0704	0100840273200253
W5-7-5	MVI	7.0 mm	5.0 mm	IFU100150	LB12173-0705	0100840273200260
W5-7-6	MVI	7.0 mm	6.0 mm	IFU100150	LB12173-0706	0100840273200277
W5-7-S	MVI	7.0 mm	5.6 mm	IFU100150	LB12175-0756	0100840273200284
W4-4-3	MVI	4.0 mm	3.0 mm	IFU100150	LB12274-0403	0100840273200291
W4-4-4	MVI	4.0 mm	4.0 mm	IFU100150	LB12274-0404	0100840273200307
W4-4-S	MVI	4.0 mm	2.6 mm	IFU100150	LB12275-0426	0100840273200314
W4-5-3	MVI	5.0 mm	3.0 mm	IFU100150	LB12274-0503	0100840273200321
W4-5-4	MVI	5.0 mm	4.0 mm	IFU100150	LB12274-0503	0100840273200338
W4-5-5	MVI	5.0 mm	5.0 mm	IFU100150	LB12274-0505	0100840273200345
W4-5-S	MVI	5.0 mm	3.6 mm	IFU100150	LB12275-0536	0100840273200352
W4-6-3	MVI	6.0 mm	3.0 mm	IFU100150	LB12274-0603	0100840273200369
W4-6-4	MVI	6.0 mm	4.0 mm	IFU100150	LB12274-0604	0100840273200376
W4-6-5	MVI	6.0 mm	5.0 mm	IFU100150	LB12274-0605	0100840273200383
W4-6-6	MVI	6.0 mm	6.0 mm	IFU100150	LB12274-0606	0100840273200390
W4-6-S	MVI	6.0 mm	4.6 mm	IFU100150	LB12275-0646	0100840273200406
W4-7-3	MVI	7.0 mm	3.0 mm	IFU100150	LB12274-0703	0100840273200413
W4-7-4	MVI	7.0 mm	4.0 mm	IFU100150	LB12274-0704	0100840273200420
W4-7-5	MVI	7.0 mm	5.0 mm	IFU100150	LB12274-0705	0100840273200437
W4-7-6	MVI	7.0 mm	6.0 mm	IFU100150	LB12274-0706	0100840273200444
W4-7-7	MVI	7.0 mm	7.0 mm	IFU100150	LB12274-0707	0100840273200451
W4-7-S	MVI	7.0 mm	5.6 mm	IFU100150	LB12275-0756	0100840273200468
W2-8-3	MVI	8.0 mm	3.0 mm	IFU100150	LB12276-0803	0100840273200475
W2-8-4	MVI	8.0 mm	4.0 mm	IFU100150	LB12276-0804	0100840273200482
W2-8-5	MVI	8.0 mm	5.0 mm	IFU100150	LB12276-0805	0100840273200499
W2-8-6	MVI	8.0 mm	6.0 mm	IFU100150	LB12276-0806	0100840273200505
W2-8-S	MVI	8.0 mm	6.6 mm	IFU100150	LB12277-0866	0100840273200512

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Catalog Number	Legal MFG	Dim "A" (D)	Dim "B" (H)	IFU Number	In-House Printed Label Box & Pouch	Product Pouch Barcode & Pouch/UDI-DI
W2-9-4	MVI	9.0 mm	4.0 mm	IFU100150	LB12276-0904	0100840273200529
W2-9-5	MVI	9.0 mm	5.0 mm	IFU100150	LB12276-0905	0100840273200536
W2-9-6	MVI	9.0 mm	6.0 mm	IFU100150	LB12276-0906	0100840273200543
W2-9-7	MVI	9.0 mm	7.0 mm	IFU100150	LB12276-0907	0100840273200550
W2-9-8	MVI	9.0 mm	8.0 mm	IFU100150	LB12276-0908	0100840273200567
W2-9-S	MVI	9.0 mm	7.6 mm	IFU100150	LB12277-0976	0100840273200574
W2-10-5	MVI	10.0 mm	5.0 mm	IFU100150	LB12278-1005	0100840273200581
W2-10-6	MVI	10.0 mm	6.0 mm	IFU100150	LB12278-1006	0100840273200598
W2-10-7	MVI	10.0 mm	7.0 mm	IFU100150	LB12278-1007	0100840273200604
W2-10-8	MVI	10.0 mm	8.0 mm	IFU100150	LB12278-1008	0100840273200611
W2-10-S	MVI	10.0 mm	8.6 mm	IFU100150	LB12279-1086	0100840273200628
W2-11-6	MVI	11.0 mm	6.0 mm	IFU100150	LB12278-1106	0100840273200635
W2-11-7	MVI	11.0 mm	7.0 mm	IFU100150	LB12278-1107	0100840273200642
W2-11-8	MVI	11.0 mm	8.0 mm	IFU100150	LB12278-1108	0100840273200659
W2-11-9	MVI	11.0 mm	9.0 mm	IFU100150	LB12278-1109	0100840273200666
W2-11-S	MVI	11.0 mm	9.6 mm	IFU100150	LB12279-1196	0100840273200673

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