EU-Examination Certificate

This is to certify that the company

MicroVention, Inc.

35 Enterprise
Aliso Viejo, CA, 92656
United States of America

EU-Representative

MicroVention Europe SARL
30 bis rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

has implemented a complete Quality Management System for each phase from Design to Final Testing of the products.

Through an audit, documented in a report, carried out by DQS Medizinprodukte GmbH, the proof was provided that this quality management system meets the requirements according to

Annex IX of the Regulation (EU) 2017/745

CONFORMITY ASSESSMENT PROCEDURE ON THE BASIS OF A QUALITY MANAGEMENT SYSTEM AND AN ASSESSMENT OF THE TECHNICAL DOCUMENTATION

regarding the medical devices listed in the Annex:
The manufacturer shall be subject to surveillance in accordance with Annex IX, Chapter 1, Section 3.
The CE marking with the identification number of the Notified Body (0297) may be affixed on the devised listed on the certificate.

Certificate registration no.	US-MF-000016658
Certificate ID	170779954
Previous certificate-ID	n/a
Effective date	2022-03-31
Expiry date	2027-03-30
Frankfurt am Main,	2022-03-31

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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Head of Certification Body

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

DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.

Annex to EU-Examination Certificate
Certificate registration No.: US-MF-000016658
Certificate ID: 170779954
Effective date: 2022-03-31

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Product name	Model	Type	Intended Use	Risk class	Basic UDI-DI
WEB™ Aneurysm Embolization System	n/a	n/a	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.	III	08402732WEBTL

Examinations and tests performed (e.g. Reference to relevant CS, harmonised standards, test reports and audit report):
420_12e_Report_TechnicalFileReview_WEB_MVI_02.docx dated 2022-03-10

Reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered:
n/a

Conditions or limitations regarding the validity of the certificate:
n/a

This annex is only valid in connection with the above-mentioned certificate.