EU Quality Management Certificate

This is to certify that the company

MicroVention, Inc.

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

SRN: US-MF-000016658

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Certificate registration no.	497135 MDR2017Q
Certificate ID	170781812
Effective date	2022-10-27
Expiry date	2027-03-30
Frankfurt am Main,	2022-10-27

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

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Digitally signed by Gribazei Alexandru
Date: 2024.07.19 13:41:13 EEST
Reason: MoldSign Signature
Location: Moldova

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 4.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000016658
Certificate ID: 170781812

Authorised Representative of the company:

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

FR-AR-000004448

Device categories covered by this certificate:

Device category:	**Prosthesis, internal, embolization, intravascular**
Risk classification:	III
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.

Device category:	**Thrombectomy suction catheter**
Risk classification:	III
Intended purpose:	The SOFIA Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. The SOFIA Catheter can be used to facilitate introduction of diagnostic or therapeutic agents. The SOFIA Catheter is not intended for use in coronary arteries. Moreover, the SOFIA Catheter is intended for use in removal/aspiration of emboli and thrombi from selected blood vessels in the arterial system, including the peripheral and neuro vasculatures.

Device category:	**Vascular guide catheter, single use**
Risk classification:	III
Intended purpose:	The SOFIA EX Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. The SOFIA EX Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA EX Catheter is not intended for use in coronary arteries.

Device category:	**Vascular Embolization Device**
Risk classification:	IIb Implantable
Intended purpose:	The AZUR system is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

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SRN of Manufacturer: US-MF-000016658
Certificate ID: 170781812

Examinations and tests performed:
497135_A208437MED_01_MDR dated 2021-09-27

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.
Products of class IIa, class IIb as well as class III listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297)
For placing class IIb implantable medical devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.
For placing class III medical devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-03-31	170777213	Addition Vascular Embolization Device, Thrombectomy suction catheter and Vascular guide catheter, single use
02	2022-08-25	170780828	Change of Intended purpose of SOFIA Catheter and SOFIA EX Catheter.