



# CERTIFICATE



This is to certify that the company

## MicroVention, Inc.

1311 Valencia Ave. Tustin, CA, 92780 United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a Quality Management System.

#### Scope:

Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres and Detachment Controller Units.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07

EN ISO 13485 : 2016 + AC : 2016

ISO 13485: 2016

Certificate registration no. 411133 MP2016

Certificate unique ID 170716796

Effective date 2018-10-31

Expiry date 2020-11-02

Frankfurt am Main 2018-10-31



**DQS Medizinprodukte GmbH** 

Sigrid Uhlemann Managing Director

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

Dr. Thomas Feldmann Head of Certification Body







Annex to certificate

Certificate registration No.: 411133 MP2016

Certificate unique ID: 170716796

**Effective date: 2018-10-31** 

## MicroVention, Inc.

1311 Valencia Ave. Tustin, CA, 92780 United States of America

#### Location

MicroVention, Inc. Production Site 35 Enterprise

Aliso Viejo, CA, 92656 United States of America

### Scope

Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres and Detachment Controller Units.

MicroVention, Inc. Production Site 1311 Valencia Ave. Tustin, CA, 92780 United States of America Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres and Detachment Controller Units.

MicroVention Costa Rica, S.R.L. Production Site Zona Franca Coyol Alajuela Costa Rica Manufacturing of Embolization Prostheses and Accessories, Intravascular Access Devices and Accessories, Stents, Embolic Protection device

