



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, Aspiration Devices 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 170758666

Effective date 2019-11-17

Expiry date 2022-11-16

Frankfurt am Main 2019-11-17



DQS Medizinprodukte GmbH

Sigrid Uhlemann Managing Director Dr. Thomas Feldmann Head of Certification Body







Annex to certificate

Certificate registration No.: 411133 MP2016

Certificate unique ID: 170758666

Effective date: 2019-11-17

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

MicroVention, Inc. Production Site

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

MicroVention Costa Rica, S.R.L. Production Site

Zona Franca Coyol Alajuela Costa Rica

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, Aspiration Devices and Detachment Controller Units.

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, Aspiration Devices and Detachment Controller Units.

Manufacturing of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheter, Guiding and Aspiration Catheters, and Microcatheters), Stents, Clot and Foreign Body Retrieval Devices, Embolic Protection System, and Aspiration Devices.

