EC DECLARATION OF CONFORMITY

FD14-0047, rev. B

We, MicroVention Europe, located in Saint-Germain-en-Laye, France declare according to Directive 93/42/EEC Annex II (incl. section 4.) under our sole responsibility that the products to which this declaration relates are in conformity with Directive 93/42/EEC and fulfill the Essential Requirements as described in Directive 93/42/EEC Annex I.

Directives	93/42/EEC	Council Directive Concerning Medical Devices
Standards	ISO 13485: 2003+AC:2009	Medical Devices – Quality management systems – Requirements for regulatory purposes
Conformity Assessment Route		Annex II, Section 4 - Full Quality System
Certificates #	**EC Design Examination:**	514729 MRA
	Full Quality Assurance:	487703 MR2

Product	Model Number(s)		Class-Rule	Effectivity date	GMDN Code
ROADSAVER™ Carotid Artery Stent System	RDS -0520-143RX RDS -0530-143RX RDS -0540-143RX RDS -0616-143RX RDS -0625-143RX RDS -0630-143RX RDS -0718-143RX RDS -0725-143RX RDS -0730-143RX	RDS -0820-143RX RDS -0825-143RX RDS -0830-143RX RDS -0840-143RX RDS -0920-143RX RDS -0930-143RX RDS -1020-143RX RDS -1030-143RX	III – Annex 9, rule 8	2014-04-07	45851

Manufacturer	**Notified Body**	**Production Site:**
MicroVention Europe 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	**DQS Medizinprodukte GmbH** Notified Body Number: 0297 D-60433 Frankfurt am Main, Germany	**MicroVention, Inc.** 1311 Valencia Avenue Tustin, CA 92780 – USA **MicroVention Costa Rica, S.R.L.** Zona Franca Coyol Alajuela, Costa Rica

Intended Use: The Carotid Artery Stent System is indicated for use in patients with atherosclerotic disease of the carotid arteries.

We herewith declare that the above-mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Sylvie Falaize
Manager Regulatory Affairs/Quality System
MicroVention Europe.

Saint-Germain-en-Laye
Place of Issue

01-July-2014
Date of Issue

Digitally signed by Grabazei Alexandru
Date: 2019.03.28 20:27:48 EET
Reason: MoldSign Signature
Location: Moldova

Expiry Date: 2018-12-26

MicroVention Europe S.A.R.L. au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 514 N
30 bis, rue du Vieil Abreuvoir – 78100 Saint-Germain-en-Laye – France Tél. : +33 (0)1 39 21 77 46 – Fax : +33 (0)1 39 21 16 01
E-mail : micro.vention@wanadoo.fr - www.microvention.com

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

MicroVention Europe

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

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Embolization Prostheses and Accessories, Intravascular Access Devices and Accessories, Stents, Clot, and Foreign Body Retrieval Devices, Liquid Embolic System, Catheter and Microspheres and Embolic Protection Devices as listed in Annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	487703 MR2
Certificate unique ID	170670045
Effective date	2016-12-27
Expiry date	2021-12-26
Frankfurt am Main	2016-12-10

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170670045
Effective date: 2016-12-27

MicroVention Europe

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

Production Sites:

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

2 MicroVention Costa Rica, S.R.L.
Zona Franca Coyol
Alajuela
Costa Rica

Distribution Site:

MicroVention, Inc.
1800 E. Wilshire Ave.
Santa Ana, CA 92705
United States of America

Device Groups:	Devices:	Risk Class	Production Site
Stents	LVIS Intraluminal Support Device LVIS Jr. Intraluminal Support Device	III	1, 2
	FRED® Flow Re-Direction Endoluminal Devices FRED Jr.® Flow Re-Direction Endoluminal Devices	III	1,2
	CASPER™ RX Carotid Artery Stent System	III	1,2
	Roadsaver™ Carotid Artery Stent System	III	1,2
	CASPER™ Peripheral Vascular Stent System	IIb	1
Clot Retriever	ERIC ™ Retrieval Device	III	1
Liquid Embolic System	PHIL™ Liquid Embolic System	III	1
Catheter	SOFIA™ Distal Access Catheter SOFIA™ PLUS Catheter SOFIA™ Guiding Catheter	III	1,2

Annex to certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170670045
Effective date: 2016-12-27

MicroVention Europe

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

Device Groups:	Devices:	Risk Class	Production Site
Microspheres	HydroPearl Microspheres LifePearl Microspheres	IIb	1
EPS – Embolic Protection Device	Empro Embolic Protection System Nanoparasol Embolic Protection System	III	1,2

CERTIFICATE

This is to certify that the company

MicroVention Europe

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

has implemented and maintains a **Quality Management System**.

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device and Microspheres.

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.	487703 MP2016
Certificate unique ID	170726669
Effective date	2018-10-31
Expiry date	2019-12-26
Frankfurt am Main	2018-10-31

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60121893 0001

Report No.: 12031336 001

Manufacturer:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products:
see attachement for products included

Replaces Approval, Registration No.: HD 60077473 0001

Expiry Date: 2022-08-29

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-08-30

Date: 2017-08-25

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60121893 0001
Report No.: 12031336 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Date: 2017-08-25

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60121893 0001
Report No.: 12031336 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products included:
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2017-08-25

M.Aihara

M.Sc. M. Aihara