TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Terumo Medical Corporation
950 Elkton Boulevard
Elkton MD 21921
USA

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope and additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-01-09
Certificate Registration No.:	SX 60125617 0001
An audit was performed. Report No.:	31690642 005
This Certificate is valid until:	2019-03-30

Digitally signed by Grabazei Alexandru
Date: 2019.03.28 19:42:27 EET
Reason: MoldSign Signature
Location: Moldova

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-01-09

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60125617 0001
Report No.: 31690642 005

Organization:
Terumo Medical Corporation
950 Elkton Boulevard
Elkton MD 21921
USA

Scope:

Scope:
Design and Development, Manufacturing and Distribution of Disposable Sterile Medical Devices, including Introducer kits, Guiding Sheaths, and Vascular Compression Cuffs. Provision of contract gamma sterilization service in accordance with EN ISO 11137-1:2015

The scope of the certification also includes the following sites:

Terumo Medical Corporation
2101 Cottontail Lane
Somerset, NJ 08873, USA
Scope: Activities related to Distribution

Terumo Medical Corporation
4550 W. Van Buren Street, Suite B-103
Phoenix, AZ 85043, USA
Scope: Activities related to Distribution

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland

Date: 2018-01-09

Dipl.-Ing. S. Pane

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60125617 0001
Report No.: 31690642 005

Organization:
Terumo Medical Corporation
950 Elkton Boulevard
Elkton MD 21921
USA

Scope:

The scope of the certification also includes the following site:

Terumo Medical Corporation
8655 Commerce Drive, Suite 101
Southaven, MS 38671, USA
Scope: Activities related to Distribution

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland

Date: 2018-01-09

Dipl.-Ing. S. Pane

DECLARATION OF CONFORMITY

We, TERUMO MEDICAL CORPORATION
950 Elkton Blvd.
Elkton, Maryland USA 21921

being the manufacturer of:

Guiding Sheath

Product: **Carotid Guiding Sheath**
Renal Guiding Sheath
Peripheral Guiding Sheath

Classification: Class IIa
Rule: **7, Invasive Device**

Hereby declares that the requirements of Annex II, excluding section 4 of the Directive 93/42/EEC have been met for the listed product. 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.

Under the supervision of TÜV Rheinland LGA Products GmbH (Registration No. HD60115912 0001) as the Notified Body according to Directive 93/42/EEC concerning medical devices with the Identification number 0197.

Authorized European Representative:
TERUMO EUROPE N.V.
Interleuvenlaan 40, B-3001
Leuven, Belgium

Elkton, Maryland USA / February 27, 2017
(Place of issue)

Kathleen Little, Ph.D.
VP, Quality and Regulatory Affairs

State of Maryland
County of Cecil

Subscribed and sworn to before me this 27 day of February month 2017 year.

Barbara C. Myers
Notary Public
My commission expires May 19, 2020

BARBARA C. MYERS NOTARY PUBLIC CECIL COUNTY, MD

K5363-Rev 7

1	2	3	4	5	
R	Radifocus Group				
	S	Guiding Sheath			
Carotid		C	90 cm Sheath		
			0	1	6 Fr, Straight Shape (ST), TBV Valve
			0	2	7 Fr, Straight Shape (ST), TBV Valve
			0	3	6 Fr, Multipurpose Shape (MP), TBV Valve
			0	4	7 Fr, Multipurpose Shape (MP), TBV Valve
			0	5	6 Fr, Straight Shape (ST), CCV Valve
			0	6	7 Fr, Straight Shape (ST), CCV Valve
			0	7	6 Fr, Multipurpose Shape (MP), CCV Valve
			0	8	7 Fr, Multipurpose Shape (MP), CCV Valve
Peripheral		P	65 cm Sheath		
			0	1	6 Fr, Straight Shape (ST), CCV Valve
			0	2	7 Fr, Straight Shape (ST), CCV Valve
			0	3	6 Fr, Straight Shape (ST), TBV Valve
			0	4	7 Fr, Straight Shape (ST), TBV Valve
Renal		R	45 cm Sheath		
			0	1	6 Fr, Straight Shape (ST), CCV Valve
			0	2	6 Fr, Hockey-Stick Shape (HS), CCV Valve
			0	3	6 Fr, Multipurpose Shape (MP), CCV Valve
			1	3	6 Fr, Renal Double Curve Shape (RDC), CCV Valve
			1	4	6 Fr, Left Internal Mammary Artery Shape (LIMA), CCV Valve
			0	4	7 Fr, Straight Shape (ST), CCV Valve
			0	5	7 Fr, Hockey-Stick Shape (HS), CCV Valve
			0	6	7 Fr, Multipurpose Shape (MP), CCV Valve
			1	5	7 Fr, Renal Double Curve Shape (RDC), CCV Valve
			1	6	7 Fr, Left Internal Mammary Artery Shape (LIMA), CCV Valve
			0	7	6 Fr, Straight Shape (ST), TBV Valve
			0	8	6 Fr, Hockey-Stick Shape (HS), TBV Valve
			0	9	6 Fr, Multipurpose Shape (MP), TBV Valve
			1	7	6 Fr, Renal Double Curve Shape (RDC), TBV Valve
			1	8	6 Fr, Left Internal Mammary Artery Shape (LIMA), TBV Valve
			1	0	7 Fr, Straight Shape (ST), TBV Valve
			1	1	7 Fr, Hockey-Stick Shape (HS), TBV Valve
			1	2	7 Fr, Multipurpose Shape (MP), TBV Valve
			1	9	7 Fr, Renal Double Curve Shape (RDC), TBV Valve
			2	0	7 Fr, Left Internal Mammary Artery Shape (LIMA), TBV Valve

1	2	3	4	5	6	7	8
5	4	Destination					
		-					
5 Fr			5				
			Straight Shape (ST), CCV Valve, Extended Coating			0	1
			Hockey Stick Shape, CCV Valve (HS)			0	2
			Multipurpose Shape, CCV Valve (MP)			0	3
			Renal Double Curve Shape, CCV Valve (RDC)			0	4
			Left Internal Mammary Artery Shape (LIMA), CCV Valve			0	5
6 Fr			6				
			Straight Shape (ST), CCV Valve, Extended Coating			0	1
			Straight Shape (ST), TBV Valve, Extended Coating			0	6
7 Fr			7				
			Straight Shape (ST), CCV Valve, Extended Coating			0	1
			Straight Shape (ST), TBV Valve, Extended Coating			0	6
8 Fr			8				
			Straight Shape (ST), CCV Valve, Extended Coating (45 & 90cm)			0	1
			Straight Shape (ST), TBV Valve, Extended Coating (45 & 90cm)			0	6
			Length	4	5	45 cm Sheath	
				6	5	65 cm Sheath	
				9	0	90 cm Sheath	

EC Certificate

TÜVRheinland®

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

Registration No.: HD 60115912 0001

Report No.: 31690642 001

Manufacturer:
Terumo Medical Corporation
950 Elkton Boulevard
Elkton MD 21921
USA

Products:
Introducer Kits and Guiding Sheaths
Aspects of manufacture concerned with securing and maintaining sterility of Vascular Compression Cuff

Replaces Approval, Registration No.: HD 60109918 0001

Expiry Date: 2022-02-16

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: 2017-02-17

Date: 2017-02-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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.