TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka, 418-0015
Japan

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

see attachments for scope of certification

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2019-03-14
Certificate Registration No.:	SX 60137046 0001
An audit was performed. Report No.:	12031333 003
This Certificate is valid until:	2020-07-09

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

Date 2019-03-14

Masahiro Asami

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®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60137046 0001
Report No.: 12031333 003

Organization:
Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka, 418-0015
Japan

Scope:

Design and Development, Manufacture, Service and Sterilization (ETO, E-beam) of
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Haemoconcentration Filter
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Blood Reservoir
- Angiographic Catheter
- Stents
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Catheter Introducer
- Wire Twister
- Guiding Catheter
- Extension Tube
- Coronary Imaging Catheters
- Centrifugal Pump
- Radial Artery Hemostasis Band

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2019-03-14

Masahiro Asami

TÜVRheinland®

Doc. 2/4, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60137046 0001
Report No.: 12031333 003

Organization:
Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka, 418-0015
Japan

Scope:

Design and Development, Manufacture, Service and Sterilization (ETO, E-beam) of

- Temperature Control Unit for Heart-Lung Bypass System Module
- Air/Fluid Level Detector for Heart-Lung Bypass System Module
- Centrifugal Pump Controller
- Syringe Infusion Pump
- Infusion Pump
- Clinical Electronic Thermometer
- Deep Body Temperature Monitor
- Clinical Electronic Blood-Pressure Meter
- Medical Equipment for Blood Collection
- Medical Equipment for APD Systems
- Sterile Tube Connecting Systems
- Coronary Optical Coherence Tomography Systems
- Blood Glucose Meters for Blood Glucose Monitoring Systems

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-03-14

Masahiro Asami

TÜVRheinland®

Doc. 3/4, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60137046 0001
Report No.: 12031333 003

Organization:
Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka, 418-0015
Japan

Scope:

Sites included:

Terumo Corporation Ashitaka Plant
150, Maimaigi-cho, Fujinomiya-shi, Shizuoka, 418-0015, JAPAN
Scope:
Activities related to Design and Development, Manufacture and Sterilization (ETO, E-beam)
Products:
Medical Devices listed on Doc. 1/4 and 2/4

Terumo Corporation - Tokyo Office
3-20-2, Nishi-Shinjuku, Shinjuku-ku, Tokyo, 163-1450 JAPAN
Scope:
Activities related to Service
Products:
Medical Devices listed on Doc. 1/4 and 2/4

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2019-03-14

Masahiro Asami

TÜVRheinland®

Doc. 4/4, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60137046 0001
Report No.: 12031333 003

Organization:
Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka, 418-0015
Japan

Scope:

Sites included:

Terumo Corporation - Shonan Center
1500, Inokuchi, Nakai-machi, Ashigarakami-gun,
Kanagawa, 259-0151 JAPAN
Scope:
Activities related to Design and Development and Service
Products:
Medical Devices listed on Doc. 1/4 and 2/4

Terumo Corporation - ME Center (Nagaizumi)
1002-1, Shimonagakubo, Nagaizumi-cho, Sunto-gun,
Shizuoka, 411-0934 JAPAN
Scope:
Activities related to Design and Development, Manufacture and Service
Products:
Medical Devices listed on Doc. 1/4 and 2/4

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2019-03-14

Masahiro Asami

TÜVRheinland®

EC Design-Examination Certificate
Directive 93/42/EEC Annex II, Section 4
Medical Devices

Registration No.: ID 60102567 0001

Report No.: 21228437 001

Manufacturer:

Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU,TOKYO 151-0072
JAPAN

Product Identification: Outlook

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60030832 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2020-06-30

Effective Date: 2015-07-01

Date: 2015-07-01

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Dr. H. Lüdemann

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.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: ID 60102567 0001
Report No.: 21228437 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU, TOKYO 151-0072
JAPAN

Scope: Angiographic Catheter Outlook

<Thoracic use>

Product code:	R	Q	□	□	□	□	□	□	□	□	□	□
Character number:	1	2	3	4	5	6	7	8	9	10	11	12

Character number	1. Characters & Meaning
1-2	Product type RQ: Outlook
3	Destination * or +/* : for worldwide excluding Japan – depending on the manufacturing location
4	Outer diameter of catheter Character : **4** **5** Size (Fr./mm) : 4 (1.40) 5 (1.70)
5-8	Indication of tip configuration: four digits are specified for each tip shape/Tip curve length
9	Number of side holes Character : 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, J Number : 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 52
10	Length Character : 4 E 5 F 6 G 7 H 8 I 9 Length (cm): 40 45 50 55 60 65 70 75 80 85 90 Character : J 0 K 1 L 2 N P Q R S Length (cm): 95 100 105 110 115 120 125 130 135 140 145 Character : T Length (cm): 150
11	Spare: 0~9, A~Z If unnecessary, omitted
12	Language for labeling M: Multi-language

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Notified Body

Dr. H. Luedemann

Date 2015-07-01

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: ID 60102567 0001
Report No.: 21228437 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU, TOKYO 151-0072
JAPAN

Scope: Angiographic Catheter Outlook

<Visceral and cerebral use>

Product code:	R	Q	□	□	□	□	□	□	□	□	□	□
Character number:	1	2	3	4	5	6	7	8	9	10	11	12

Character number	2. Characters & Meaning
1-2	Product type **RQ**: Outlook
3	Destination * or +/* : for worldwide excluding Japan – depending on the manufacturing location
4	Indication of catheter use **A**: Abdominal & Peripheral (Visceral use) **B**: Cerebral use
5-6	Indication of tip configuration/number of side holes: two digits are specified for each tip shape
7	Catheter size O.D. **4**: 4 Fr. (1.40 mm)
8	Availability of stopcock **1** : without stopcock
9-10	Catheter Length

Characters :	04	0E	05	0F	06	0G	07	0H	08	0I	09
Length (cm):	40	45	50	55	60	65	70	75	80	85	90
Character :	0J	10	1A	11	1B	12	1C	13	1D	14	1E
Length (cm):	95	100	105	110	115	120	125	130	135	140	145
Character :	15										
Length (cm):	150										

11	Languages used for the indications **M**: Multilanguage
12	Special product indication : alphanumerical digit to distinguish from standard items

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Dr. H. Luedemann

Date 2015-07-01

TÜVRheinland®

EC Design-Examination Certificate

Directive 93/42/EEC Annex II, Section 4

Medical Devices

Registration No.: ID 60102630 0001

Report No.: 21228431 001

Manufacturer:

Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU,TOKYO 151-0072
JAPAN

Product Identification:

Radifocus Glidecath

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60030799 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2020-06-30

Effective Date: 2015-07-01

Date: 2015-07-01

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. H. Lüdemann

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: ID 60102630 0001
Report No.: 21228431 002

Manufacturer:
Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU, TOKYO 151-0072
JAPAN

Scope: Angiographic Catheter Radifocus Glidecath

Product code:	R	F	*	□	□	□	□	□	□	□	□	□
Character number:	1	2	3	4	5	6	7	8	9	10	11	12

Character number	1. Characters & Meaning
1-2	Product name RF: Radifocus
3	Destination * : for export
4	Applied region **X:** Renal & Visceral, **Y:** Cerebral (for single braided) **Z:** Renal & Visceral, **W:** Cerebral (for double braided)
5-6	Indication of tip configuration: these two digits together with digit 4 makes an unique code specific for each shape and number of side holes
7	Outer diameter of catheter Indication: **4** **5** Diameter (Fr/mm): 4 (1.40) 5 (1.70)
8	Indication of two-way stopcock without two-way stopcock : 1
9-10	Catheter length

Character :	02	0C	03	0D	04	0E	05	0F	06	0G	07
Length (cm):	20	25	30	35	40	45	50	55	60	65	70
Character :	0H	08	0I	09	0J	10	1A	11	1B	12	1C
Length (cm):	75	80	85	90	95	100	105	110	115	120	125
Character :	13	1D	14	1E	15						
Length (cm):	130	135	140	145	150						

Date 2015-11-17

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body
Dr. H. Luedemann

TÜVRheinland®

Doc. 2/2, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Registration No.: ID 60102630 0001
Report No.: 21228431 002

Manufacturer:
Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU, TOKYO 151-0072
JAPAN

Scope: Angiographic Catheter Radifocus Glidecath

Product code:	R	F	*	□	□	□	□	□	□	□	□	□
Character number:	1	2	3	4	5	6	7	8	9	10	11	12

Character number	Characters & Meaning
11	Hydrophilic coating length Character : **1** **2** **3** **4** **5** **6** **7** **8** **9** **F** **G** Length (cm): 1 2 3 4 5 6 7 8 9 20 25 Character : **H** **I** **J** **K** **L** Length (cm): 30 35 40 45 50 Eleventh character is omitted for all catheters with hydrophilic coating length of 15 cm.
12	Language for labeling **M** = Multilanguage **A** = Multilanguage (sold in USA)

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Dr. H. Luedemann

Date 2015-11-17

TÜVRheinland®

EC Design-Examination Certificate
Directive 93/42/EEC Annex II, Section 4
Medical Devices

Registration No.: ID 60114893 0001

Report No.: 21257349 001

Manufacturer:

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

Product Identification:

Catheter, Angiography
RADIFOCUS OPTITORQUE

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60041976 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2021-11-10

Effective Date: 2016-11-11

Date: 2016-11-10

Notified Body

Dipl.-Ing. S. Pane

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: **ID 60114893 0001**
Report No.: **21257349 001**

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

Radifocus Optitorque

Product code system

(1) Thoracic use

R	H	+/*	□	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11	12

Position	Characters & Meaning
1-2	Product type RH: Radifocus® Optitorque™
3	Destination * : for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) + / *: for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co., Ltd)
4	Outer diameter of catheter Character: 4 5 6 Diameter: 4 Fr. (1.40 mm) 5 Fr. (1.70 mm) 6 Fr. (2.00 mm)
5-8	Tip shape: Character (A~Z, 0~9)
9	Number of side holes Character: 0 ~ 9, J, K, L, T Number of side holes: 0 - 9, 52, 20, 50, 4 (special)
10	Catheter Length Character: 4 E 5 F 6 G 7 H 8 I 9 Length (cm): 40 45 50 55 60 65 70 75 80 85 90 Character : J 0 K 1 L 2 N Length (cm): 95 100 105 110 115 120 125 * The maximum catheter length for the following tip shapes is 100 cm: 3D-Right Modified and 3D RC
11	Braid cut length: Q: 60 mm (For products whose braid cut length is not 60 mm, the product code consists of 11 characters and the 11th position indicates the language for labelling)
12	Languages used for the indication M: Multi-language indication

Notified Body

Date 2016-11-10

Dipl.-Ing. S. Pane

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: ID 60114893 0001
Report No.: 21257349 001

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

Radifocus Optitorque

(2) Visceral & Cerebral use

R	H	+/*	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Position	Characters & Meaning
1-2	Product type RH: Radifocus Optitorque™
3	Destination *: for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) + / *: for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co., Ltd)
4	Indication of catheter use: A : visceral use B : cerebral use
5-6	Tip shape: Character (A~Z, 0~9)
7	Outer diameter of catheter Character: 4 5 Diameter: 4 Fr. (1.40 mm) 5 Fr. (1.70 mm)
8	Availability of stopcock 1 : Without stopcock
9-10	Length
	Character: 02 03 04 05 06 0G 07 0H 08 0I 09 Length (cm): 20 30 40 50 60 65 70 75 80 85 90
	Character: 0J 10 1A 11 1B 12 1C Length (cm): 95 100 105 110 115 120 125
11	Language used for the indications M: Multi-language

TÜV Rheinland LGA Products GmbH
Notified Body

Date 2016-11-10

Dipl.-Ing. S. Pane

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.

TÜVRheinland®

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

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

Design and development, manufacture and distribution of active, non-active medical devices and IVD medical devices and servicing of active medical devices (see attachments for products and sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2018-12-28
Certificate Registration No.:	SX 60135471 0001
An audit was performed. Report No.:	12031336 004
This Certificate is valid until:	2020-08-29

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-12-28

Masahiro Asami

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®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60135471 0001
Report No.: 12031336 004

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

Scope:

Products included:

- Solution Administration Sets
- Needles
- Syringes
- IV Catheters
- Blood Collection Systems
- Sterile Tube Connecting Systems
- Blood Glucose Monitoring Systems
- Stents
- Catheter and Guide Wire Systems
- Oxygenator Systems
- Extension Tube
- Blood Transfusion Systems
- Apheresis Systems
- Filter Systems
- Infusion Pumps
- Syringe Infusion Pumps

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-12-28

Masahiro Asami

TÜVRheinland®

Doc. 2/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60135471 0001
Report No.: 12031336 004

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

Scope:

Products included:

- Clinical Electronic Blood-Pressure Monitors
- Clinical Electronic Thermometer
- Medical Equipments for Blood Collection
- Medical Equipments for APD Systems
- Vascular Grafts
- Coronary Optical Coherence Tomography Systems
- Prefillable Syringes

Site included:

Terumo Corporation - Tokyo Office
3-20-2, Nishi-Shinjuku, Shinjuku-ku, Tokyo, 163-1450 Japan

Scope:
Activities related to corporate management processes

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2018-12-28

Masahiro Asami

TÜVRheinland®

Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60135471 0001
Report No.: 12031336 004

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

Scope:

Site included:

Terumo Corporation - Shonan Center
1500, Inokuchi, Nakai-machi, Ashigarakami-gun, Kanagawa, 259-0151, Japan

Scope:
Activities related to customer communication processes and distribution of active, non-active and IVD medical devices

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

Certification Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2018-12-28

Masahiro Asami

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

TERUMO VIETNAM CO., LTD.
Lot 44A-B-C, Quang Minh
Industrial Zone, Me Linh District
Hanoi City
Vietnam

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

Design and Development, Manufacture of Catheter Introducer, Angiographic Catheter and Catheter Guide Wire
Manufacture of Vascular and Endovascular Stented Assemblies

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2019-03-13
Certificate Registration No.:	SX 60137049 0001
An audit was performed. Report No.:	12031318 003
This Certificate is valid until:	2020-01-15

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2019-03-13

Masahiro Asami

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®

EC Design-Examination Certificate

Directive 93/42/EEC Annex II, Section 4

Medical Devices

Registration No.: ID 60102632 0001

Report No.: 21228431 001

Manufacturer:

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Product Identification:

Radifocus Glidecath

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60041721 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2020-06-30

Effective Date: 2015-07-01

Date: 2015-07-01

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland

Dr. H. Lüdemann

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: ID 60102632 0001
Report No.: 21228431 001

Manufacturer:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgien

Scope: Angiographic Catheter Radifocus Glidecath

Product code:	R	F	-	□	□	□	□	□	□	□	□
Character number:	1	2	3	4	5	6	7	8	9	10	11

Character number	Characters & Meaning
1-2	Product name **RF**: Radifocus
3	Manufacturing site **-** : manufactured at Terumo Europe N.V.
4	Indication of catheter use & structure **W** : Cerebral, double braided **X** : Abdominal & peripheral, single braided **Y** : Cerebral, single braided **Z** : Abdominal & peripheral, double braided
5-6	Indication of tip configuration: these two digits together with digit 4 makes an unique code specific for each shape and number of side holes.
7	Outer diameter of catheter Indication: **4** **5** Diameter (Fr/mm): 4 (1.40) 5 (1.70)
8	Indication of two-way stopcock without two-way stopcock : 1
9-10	Catheter length Indication: **04** **0G** **07** **08** **09** **10** **11** Length (cm): 40 65 70 80 90 100 110
11	Packaging indication **M** : Multi-language indication

Date 2015-07-01

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dr. H. Luedemann

TÜVRheinland®

EC Design-Examination Certificate
Directive 93/42/EEC Annex II, Section 4
Medical Devices

Registration No.: ID 60114894 0001

Report No.: 21255836 001

Manufacturer:

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Product Identification:

Catheter, Angiography
RADIFOCUS OPTITORQUE

(see attachment for products included)
Replaces certificate, Registration No.: ID 60041981 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2021-11-10

Effective Date: 2016-11-11

Date: 2016-11-09

Notified Body

TÜV Rheinland LGA Products GmbH

Dipl.-Ing. S. Pane

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: **ID 60114894 0001**
Report No.: **21255836 001**

Manufacturer: **TERUMO EUROPE N.V.**
Interleuvenlaan 40
3001 Leuven
Belgium

Radifocus Optitorque

Product code system

(1) Thoracic use

R	H	-	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning
1-2	Product name RH: Radifocus® Optitorque™
3	Manufacturing site -: TERUMO Europe N.V.
4	Outer diameter of catheter Indication: 4, 5 6 Size (Fr.): 4 (1.40 mm); 5 (1.70 mm); 6 (2.00 mm)
5-8	Tip shape: Character (A~Z, 0~9)
9	Number of side holes Indication: 0 ~ 9 Number of side holes: 0 - 9
10	Catheter Length
	Indication : 6 G 7 8 9 0 1 Length (cm): 60 65 70 80 90 100 110
11	Language used for the indications M: Multi-language indication

Date, 2016-11-09

Notified Body

Dipl.-Ing. S. Pane

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: **ID 60114894 0001**
Report No.: **21255836 001**

Manufacturer: **TERUMO EUROPE N.V.**
Interleuvenlaan 40
3001 Leuven
Belgium

Radifocus Optitorque

(2) Visceral & Cerebral use

R	H	-	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning
1-2	Product name RH: Radifocus® Optitorque™
3	Production site -: TERUMO Europe N.V.
4	Indication of catheter use A : visceral use B : cerebral use
5-6	Tip shape: Character (A~Z, 0~9)
7	Outer diameter of catheter Indication: 4, 5 Size (Fr.): 4 (1.40 mm); 5 (1.70 mm)
8	Availability of stopcock 1 : Without stopcock
9-10	Catheter Length
	Indication: 02 0G 07 08 09 10 11 Length (cm): 20 65 70 80 90 100 110
11	Languages used for the indication M: Multilanguage

TÜV Rheinland LGA Products GmbH
Notified Body

Date, 2016-11-09

Dipl.-Ing. S. Pane

TÜVRheinland®

EC Design-Examination Certificate

Directive 93/42/EEC Annex II, Section 4

Medical Devices

Registration No.: ID 60102568 0001

Report No.: 21228437 001

Manufacturer:

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Product Identification:

Outlook
- Single unit packs
- Three unit packs "Tri-pack"

(see attachment for products included)
Replaces Certificate, Registration No.: ID 60038081 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2020-06-30

Effective Date: 2015-07-01

Date: 2015-07-01

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland

Dr. H. Lüdemann

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.

TÜVRheinland®

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TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: ID 60102568 0001
Report No.: 21228437 001

Manufacturer:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope: Angiographic Catheter "Outlook"

Product code: R Q - □ □ □ □ □ □ □ □ □ □
Character number: 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters & Meaning		
1-2	Product type: **RQ** Radifocus Outlook		
3	Production site: -Terumo Europe N.V.		
	Thoracic Use	**Others**	**Three Unit Pack**
4	Catheter size O. D.: **4**: 4Fr (1.40mm)	Indication of catheter use	Indication of packaging way **MK**: Multi-pack
5	Indication of tip configuration: four digits are specified for each tip shape/Tip curve length	Indication of tip configuration/number of side holes: two digits are specified for each tip shape	
6			Catheter size O. D.: **4**: 4Fr (1.40mm)
7		Catheter size O. D.: **4**: 4Fr (1.40mm)	Tip shape of coronary catheter
8		Availability of stopcock 1: without stopcock	Tip configuration of coronary catheter
9	Number of holes: Character: 0 ~ 8 Number: 0 ~ 8	Catheter length: 20 ~ 110 cm	Ventricular catheter
10	Catheter length: 65 ~ 110 cm one digit specifies the length		Languages used for the indications **M**: Multilanguage
11	Languages used for the indications **M**: Multilanguage	Languages used for the indications **M**: Multilanguage	Special product indication
12	Special product indication	Special product indication	

Date 2015-07-01

Notified Body

Dr. H. Luedemann

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

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

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2018-12-08
Certificate Registration No.:	SX 60134689 0001
An audit was performed. Report No.:	21240046 013
This Certificate is valid until:	2021-12-07

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

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. 1/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope:

Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories.

Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices.

Servicing of active medical devices.

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 2/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope:

additional sites included:

Terumo Europe N.V., European Distribution Center
Brikkenovenstraat 48, 3600 Genk, Belgium

Activities: Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Terumo Europe N.V., Terumo Europe UK Manufacturing
3 Unity Grove, Knowsley Business Park South
Knowsley, Merseyside L34 9GT, United Kingdom

Activities: Design and development, manufacture and sterilization of extra corporeal circuits for open heart surgery and ancillary devices

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 3/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope:

additional sites included:

Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices:

Terumo Europe N.V.
Terumo Interventional Systems - EMEA (TIS-EMEA)
Interleuvenlaan 40, 3001 Leuven, Belgium

Terumo Europe N.V., Terumo Cardiovascular Europe, Middle East & Africa (TCV-EMEA)
Ludwig-Erhard-Straße 6, 65760 Eschborn, Germany

Terumo Europe N.V., Terumo Medical Products EMEA (TMP-EMEA)
Interleuvenlaan 40, 3001 Leuven, Belgium

Terumo Europe N.V., Diabetes Management EMEA (DM-EMEA)
Interleuvenlaan 40, 3001 Leuven, Belgium

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

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 4/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope:

additional sites included:

Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnotic medical devices:

Terumo Deutschland GmbH
Ludwig-Erhard-Straße 6, 65760 Eschborn, Germany

Terumo Deutschland GmbH, Zweigniederlassung Switzerland
Bodenäckerstrasse 3, 8957 Spreitenbach, Switzerland

Terumo Deutschland GmbH, Zweigniederlassung Austria
Liebermannstrasse F10-301, 2345 Brunn am Gebirge, Austria

Terumo Europe España SL
Avda. Juan Carlos I, Nº13-7 Planta, Edificio Torre La Garena
28806 Alcalá de Henares (Madrid), Spain

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 5/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope:

additional sites included:

Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnotic medical devices:

Terumo Europe N.V., Emerging Market Division
Interleuvenlaan 40, 3001 Leuven, Belgium

Terumo Italia S.r.l.
Via Paolo di Dono 73, 00142 Roma, Italy

Terumo France S.A.S.
Bâtiment Renaissance, 3 rond-point des Saules,
78280 Guyancourt, France

Terumo Sweden AB
Sven Källfets gata 18,
426 71 Västra Frölunda, Sweden

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 6/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope:

additional sites included:

Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnotic medical devices:

Terumo Europe UK Ltd.
Otium House, 2 Freemantle Road, Bagshot Surrey GU19 5LL, UK

Terumo Poland Sp. Zoo
Wisniowy Business Park budynek D, ul. 1 Sierpnia 6
02-134 Warszawa, Poland

Terumo Europe N.V., Benelux Sales Division
Interleuvenlaan 40, 3001 Leuven, Belgium

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 7/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope:

additional sites included:

Marketing and distribution of active and non-active medical devices:

Terumo Europe N.V., Terumo Pharmaceutical Solutions
Interleuvenlaan 40, 3001 Leuven, Belgium

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

EC Certificate

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

Registration No.: HD 60106290 0001

Report No.: 21240046 001

Manufacturer:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products: (see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60035711 0001

Expiry Date: 2020-12-07

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: 2015-12-08

Date: 2015-12-08

Notified Body

Dipl.-Ing. D. Meier

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.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60106290 0001
Report No.: 21240046 001

Manufacturer:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products:

- Syringes
- Needles
- Administration sets
- Blood collecting systems
- Angiographic-interventional catheter systems
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles
- Blood collecting systems

Date: 2015-12-08

Notified Body

Rheinland LGA Products GmbH TÜVRheinland® Zertifizierstelle

Dipl.-Ing. D. Meier

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60106290 0001
Report No.: 21240046 001

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Additional sites included:

TERUMO EUROPE N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium

Scope: Warehouse operations and distribution of medical devices

TERUMO UK
3 Unity Grove
Knowsley Business Park South, Knowsley,
Merseyside L34 9GT, United Kingdom

Scope: Design and development, manufacture of extracorporeal circuits for open heart surgery and ancillary circuits

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. D. Meier

Date: 2015-12-08