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

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

Digitally signed by Grabazei Alexandru
Date: 2019.03.28 19:45:35 EET
Reason: MoldSign Signature
Location: Moldova

Effective Date:	2017-07-10
Certificate Registration No.:	SX 60120892 0001
An audit was performed. Report No.:	12031333 001
This Certificate is valid until:	2019-03-30

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date 2017-07-03

M.Sc. M. Aihara

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 60120892 0001
Report No.: 12031333 001

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

Scope:

Design and Development, Manufacture, Service and Sterilization (ETO) 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

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2017-07-03

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/4, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60120892 0001
Report No.: 12031333 001

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

Scope:

Design and Development, Manufacture, Service and Sterilization (ETO) 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: 2017-07-03

M.Aihara

M.Sc. M. Aihara

TÜVRheinland®

Doc. 3/4, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60120892 0001
Report No.: 12031333 001

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)
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

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2017-07-03

M.Sc. M. Aihara

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Doc. 4/4, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60120892 0001
Report No.: 12031333 001

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
Monitoring Systems

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2017-07-03

M. Aihara

M.Sc. M. Aihara

By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 580672**

Issued To: **Terumo Corporation**
44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
151-0072
Japan

In respect of:

Progreat Angiographic Catheters

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **23 December 2011** Date: **18 November 2016** Expiry Date: **22 December 2021**

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EC Design-Examination Certificate

Supplementary Information to CE 580672

Issued To:

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

Product code system: Step-by-step flexibility type

M	C	-	□	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11	12

Character number	What the character(s) represents	Denotation			
1 - 2	Product	MC: Micro Catheter			
3	Destination	- : For domestic use/export (except U.S.A.)			
4	Trade name	P: Progreat			
5	Specification		**Guide wire type**	**Tip shape of guide wire**	**Tip shape of catheter/ Radiopaque marker specification**
		A	Without guide wire	Without guide wire	Angled/without marker***
		B	Without guide wire	Without guide wire	Straight/single marker
		C	Without guide wire	Without guide wire	Straight/without marker**
		E	Reshapeable	Angled	Straight/without marker
		P	Pre-shaped	Angled	Straight/without marker
		U	Without guide wire	Without guide wire	Straight/double marker (Type A)
		V	Without guide wire	Without guide wire	Straight/double marker (Type B)

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Japan

Character number	What the character(s) represents	Denotation			
			Guide wire type	**Tip shape of guide wire**	**Tip shape of catheter/Radiopaque marker specification**
		X	Without guide wire	Without guide wire	90º-angled/without marker
6 – 7	Catheter O.D. at distal end	20	24	27	28	
		2.0Fr.	2.4Fr.	2.7Fr.	2.8Fr.	

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Character number	What the character(s) represents	Denotation										
8 – 9	Usable length of catheter	10	0C	11	1C	12	2C	13	3C	14	4C	15
		100cm	105cm	110cm	115cm	120cm	125cm	130cm	135cm	140cm	145cm	150cm
10	Protruding length of guide wire *	A	0	B	2	C	3	D	4	E	5	F	6
		5mm	10mm	15mm	20mm	25mm	30mm	35mm	40mm	45mm	50mm	55mm	60mm
		G	7	H	8	J	9	K	1	L	M		
		65mm	70mm	75mm	80mm	85mm	90mm	95mm	100mm	110mm	120mm		
		N	P	Q	R	S	T	U	V	W			
		130mm	140mm	150mm	160mm	170mm	180mm	190mm	200mm	250mm			
11	Kit contents	**(Blank): Standard** • With guide wire in the same holder: Catheter mandrel, Lock-type syringe, Inserter, Wire stopper • W/o guide wire: Catheter Mandrel **Modified type of standard:** Y: Standard kit + Y-connector										

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Character number	What the character(s) represents	Denotation
12	Specifications	Blank if unnecessary
	With a marker at the catheter tip (if a guide wire is attached)	B (for standard kit, the eleventh character is "Z".)

*: For product w/o guide wire, the 10th character is skipped and the 11th and 12th characters are shifted to the left

**: For catheter O.D. at distal end 2.0Fr., without marker type doesn't exist and "C" is used instead of "B"

***: 2.0Fr. type is equipped with single marker

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Supplementary Information to CE 580672

Issued To:

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

Stepless flexibility type

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

Character number	What the character(s) represents	Denotation	
1 - 2	Radiopaque marker specification	MC : (Micro Catheter) Single marker MW: (Micro Catheter) Double marker	
3	Destination	- : For domestic use/ export (except U.S.A.)	
4	Simple catheter, Catheter with GW	C: Simple catheter	
5	Specification	A	With angled catheter tip
		C	Standard

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Character number	What the character(s) represents	Denotation										
6	Catheter O.D. at distal end	2 2.2Fr.										
7	Usable length of catheter	A 85cm	B 95cm	0 100cm	C 105cm	1 110cm	D 115cm	2 120cm	E 125cm	3 130cm	F 135cm	4 140cm
		G 145cm	5 150cm									
8	*1	Z										
9	*1	Z										
10	*1	Z										
11	Kit contents	Y: Standard kit + Y-connector										

*1: When additional characters are required for products without-GW

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The following symbols are added depending on the outer diameter of the distal tip of the catheter:

Catheter O.D.	Symbol
2.0Fr.	α
2.2Fr.	β^3
2.4Fr.	-
2.7Fr.	-
2.8Fr.	Ω

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Certificate History

Date	Reference Number	Action
23 December 2011	10131540	NB Transfer and certificate renewal.
16 March 2016	10159714	Change affecting Tyvek ®1073 B and Tyvek® 1059B packaging materials- all product codes are affected.
18 November 2016	10166569	Certificate renewal. Added additional product code explanation. Corrected error in 'E' and 'P' in character 5 from 'with marker to 'without marker'.

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