



AGENTIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declarația de conformitate CE

Введите текст для поиска...										
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Prodicatorul	Reprezentant	Ordin	Data	Cod V
		Progreat				Terumo				
DM000192213	Microcateter pentru angiografie	Progreat®	Microcatheter	MC-PE28131ZB	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192208	Microcateter pentru angiografie	Progreat®	Microcatheter	MC-PX2413	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192211	Microcateter pentru angiografie	Progreat®	Microcatheter	MC-PP27131	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192209	Microcateter pentru angiografie	Progreat®	Microcatheter	MC-PV2415Y	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192212	Microcateter pentru angiografie	Progreat®	Microcatheter	MC-PC2813	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192203	Microcateter pentru angiografie	Progreat®	Microcatheter	MC-PC2013	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192214	Microcateter pentru angiografie	Progreat®	Microcatheter	MC-PV2815Y	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192205	Microcateter pentru angiografie	Progreat®	Microcatheter	MC-PC2413	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
Страница 2 из 2 (Всего элементов: 18) ⏪ 1 2 ⏩										
<input checked="" type="checkbox"/> 🔍 Содержит(Prodicatorul), 'Terumo') И Содержит(NameMake), 'Progreat')										

Progreat®

Micro Catheter System



Progreat® microcatheter system is designed for therapeutic embolization and angiography in peripheral vessels. It gives control with ease of use, kink resistance and distal flexibility.

Product Characteristics

- Coaxial Wire Protruding Length 10cm
- Radiopaque gold coil Guidewire
- PTFE inner layer
- 0.7mm radiopaque platinum/iridium marker
- Outer layer with M-Coat
- Radiopaque tungsten spiral coil
- Coaxial System allows fast and smooth procedures through wire integration and easy microcatheter preparation
- Tungsten spiral coil and three layer structure protect inner lumen integrity for smooth delivery of all types of embolic material ¹
- Varied pitch of tungsten spiral coil with Terumo's hydrophilic coating provides flexibility thus notably increasing its distal selectivity in tortuous and narrow vessels ¹

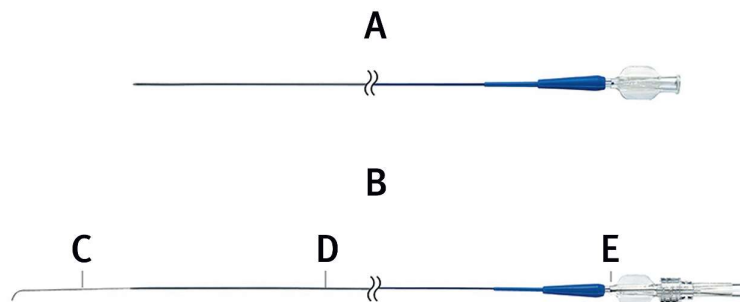
Compatible agents:

- Pushable coils to 0.018
- NBCA glue
- Ethanol
- Lipiodol ²
- Chemoembolization agents (Epirubicin, Cisplatin, Mitomycin, Doxorubicin, Zinostatin)
- Maximum beads size is different for each catheter size
- DMSO ³
- Any kind of usual contrast media

¹ Bench testing done by Terumo Corporation. Data on file (TC-Pro107). Bench test data are not necessarily indicative of clinical performance.

² Lipiodol is a brand name of Guerbet.

³ Performance testing done by Terumo Corporation. Data on file (TC-Pro108). Physical performance testing on Progreat microcatheter exposed to DMSO under controlled conditions.



A Progreat 2.0 Fr / 2.4 Fr / 2.7 Fr / 2.8 Fr microcatheter (without guidewire)

B Progreat 2.4 Fr / 2.7 Fr / 2.8 Fr microcatheter system (coaxial type with catheter and guidewire)

C Guidewire

D Catheter shaft

E Hub

General specifications

Catheter Inner Layer	PTFE
Catheter Medium Layer	Radiopaque Tungsten Coil
Catheter Outer Layer	Polyester Elastomer, Polyurethane Elastomer and Pigment
Guidewire core material (for coaxial versions)	Nitinol
Guidewire Core Material (for Coaxial Versions)AC	Nitinol
Guidewire distal marker (for coaxial versions)	2 or 3 cm Gold Coil
Guidewire outer layer material (for coaxial versions)	Polyurethane Layer Containing Tungsten
Guidewire Protruding Length (for Coaxial Versions)	10 cm Maximum
Hydrophilic Coating	M Coat™ Polymer

Item specifications

Outer Diameter	Length	Inner Diameter	Distal Curve	Guidewire Compatibility	Marker	Maximum pressure	Dead Volume (Hub + Catheter)	Description	Code
2.0 Fr 0.67 mm	110 cm	0.019 in 0.49 mm	Straight (shapeable)	0.016 in 0.41 mm	1	750 psi 5171 kPa	0.28 ml	Progreat 2.0 Fr	MC-PC2011
2.0 Fr 0.67 mm	130 cm	0.019 in 0.49 mm	Straight (shapeable)	0.016 in 0.41 mm	1	750 psi 5171 kPa	0.32 ml	Progreat 2.0 Fr	MC-PC2013
2.0 Fr 0.67 mm	150 cm	0.019 in 0.49 mm	Straight (shapeable)	0.016 in 0.41 mm	1	750 psi 5171 kPa	0.38 ml	Progreat 2.0 Fr	MC-PC2015
2.4 Fr 0.80 mm	110 cm	0.022 in 0.57 mm	Straight	0.018 in 0.46 mm	1	750 psi 5171 kPa	0.38 ml	Progreat 2.4 Fr Coaxial	MC-PP24111ZD
2.4 Fr 0.80 mm	110 cm	0.022 in 0.57 mm	Straight	0.018 in 0.46 mm	1	750 psi 5171 kPa	0.38 ml	Progreat 2.4 Fr Coaxial	MC-PP24111ZB
2.4 Fr 0.80 mm	110 cm	0.022 in 0.57 mm	Straight (shapeable)	0.018 in 0.46 mm	0	750 psi 5171 kPa	0.38 ml	Progreat 2.4 Fr	MC-PC2411
2.4 Fr 0.80 mm	130 cm	0.022 in 0.57 mm	Straight	0.018 in 0.46 mm	1	750 psi 5171 kPa	0.43 ml	Progreat 2.4 Fr Coaxial	MC-PP24131ZB
2.4 Fr 0.80 mm	130 cm	0.022 in 0.57 mm	Straight	0.018 in 0.46 mm	1	750 psi 5171 kPa	0.43 ml	Progreat 2.4 Fr Coaxial	MC-PP24131ZD
2.4 Fr 0.80 mm	130 cm	0.022 in 0.57 mm	Straight (shapeable)	0.018 in 0.46 mm	0	750 psi 5171 kPa	0.43 ml	Progreat 2.4 Fr	MC-PC2413
2.4 Fr 0.80 mm	130 cm	0.022 in 0.57 mm	Straight (shapeable)	0.018 in 0.46 mm	1	750 psi 5171 kPa	0.43 ml	Progreat 2.4 Fr	MC-PB2413
2.4 Fr 0.80 mm	130 cm	0.022 in 0.57 mm	90° Angle	0.018 in 0.46 mm	0	750 psi 5171 kPa	0.43 ml	Progreat 2.4 Fr	MC-PX2413
2.4 Fr 0.80 mm	150 cm	0.022 in 0.57 mm	Straight	0.018 in 0.46 mm	2	750 psi 5171 kPa	0.47 ml	Progreat 2.4 Fr Coaxial	MC-PP24151ZW
2.4 Fr 0.80 mm	150 cm	0.022 in 0.57 mm	Straight	0.018 in 0.46 mm	2	750 psi 5171 kPa	0.47 ml	Progreat 2.4 Fr Coaxial	MC-PP24151ZV
2.4 Fr 0.80 mm	150 cm	0.022 in 0.57 mm	Straight (shapeable)	0.018 in 0.46 mm	0	750 psi 5171 kPa	0.47 ml	Progreat 2.4 Fr	MC-PC2415
2.4 Fr 0.80 mm	150 cm	0.022 in 0.57 mm	Straight (shapeable)	0.018 in 0.46 mm	2 (3 cm proximal to distal)	750 psi 5171 kPa	0.47 ml	Progreat 2.4 Fr	MC-PV2415Y
2.7 Fr 0.90 mm	110 cm	0.025 in 0.65 mm	Straight (shapeable)	0.021 in 0.53 mm	0	750 psi 5171 kPa	0.46 ml	Progreat 2.7 Fr Coaxial	MC-PE27111
2.7 Fr 0.90 mm	110 cm	0.025 in 0.65 mm	Straight (shapeable)	0.021 in 0.53 mm	0	750 psi 5171 kPa	0.46 ml	Progreat 2.7 Fr Coaxial	MC-PE27115
2.7 Fr 0.90 mm	110 cm	0.025 in 0.65 mm	Straight (shapeable)	0.021 in 0.53 mm	0	750 psi 5171 kPa	0.46 ml	Progreat 2.7 Fr Coaxial	MC-PP27111
2.7 Fr 0.90 mm	130 cm	0.025 in 0.65 mm	Straight (shapeable)	0.021 in 0.53 mm	0	750 psi 5171 kPa	0.53 ml	Progreat 2.7 Fr Coaxial	MC-PE27131
2.7 Fr 0.90 mm	130 cm	0.025 in 0.65 mm	Straight (shapeable)	0.021 in 0.53 mm	0	750 psi 5171 kPa	0.53 ml	Progreat 2.7 Fr Coaxial	MC-PP27131
2.7 Fr 0.90 mm	150 cm	0.025 in 0.65 mm	Straight (shapeable)	0.021 in 0.53 mm	0	750 psi 5171 kPa	0.59 ml	Progreat 2.7 Fr	MC-PC2715
2.7 Fr 0.90 mm	150 cm	0.025 in 0.65 mm	Straight (shapeable)	0.021 in 0.53 mm	0	750 psi 5171 kPa	0.59 ml	Progreat 2.7 Fr Coaxial	MC-PP27151
2.8 Fr 0.93 mm	130 cm	0.027 in 0.70 mm	Straight (shapeable)	0.021 in 0.53 mm	0	900 psi 6205 kPa	0.59 ml	Progreat 2.8 Fr	MC-PC2813
2.8 Fr 0.93 mm	130 cm	0.027 in 0.70 mm	Straight (shapeable)	0.021 in 0.53 mm	0	900 psi 6205 kPa	0.59 ml	Progreat 2.8 Fr	MC-PP28131
2.8 Fr 0.93 mm	130 cm	0.027 in 0.70 mm	Straight (shapeable)	0.021 in 0.53 mm	0	900 psi 6205 kPa	0.59 ml	Progreat 2.8 Fr	MC-PE28131
2.8 Fr 0.93 mm	130 cm	0.027 in 0.70 mm	Straight (shapeable)	0.021 in 0.53 mm	1	900 psi 6205 kPa	0.59 ml	Progreat 2.8 Fr	MC-PE28131ZB
2.8 Fr 0.93 mm	150 cm	0.027 in 0.70 mm	Straight (shapeable)	0.021 in 0.53 mm	2 (3 cm proximal to distal)	900 psi 6205 kPa	0.66 ml	Progreat 2.8 Fr	MC-PV2815Y
2.8 Fr 0.93 mm	150 cm	0.027 in 0.70 mm	Straight (shapeable)	0.021 in 0.53 mm	2 (3 cm proximal to distal)	900 psi 6205 kPa	0.66 ml	Progreat 2.8 Fr Coaxial	MC-PE28151ZV

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION

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

being the manufacturer of:

Progreat

Angiographic Catheter

Product : Angiographic Catheter

declare that the above products of **Class III** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II excluding Section 4 (Certificate No.: CE 554734), and Annex II Section 4 (Certificate No.: CE 580672) under the supervision of BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, as Notified Body authorized by the Netherlands Competent Authority and carrying the Notified Body No. 2797.

Authorized European Representative:

TERUMO EUROPE N.V.

Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, March 12, 2019

(place and date of issue)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION

Appendix A - List of Code Number Structure

<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			
		Q	Pre-shaped				Double 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)			
X	Without guide wire				Without guide wire			90°-angled/ without marker					
6 - 7	Catheter O.D. at distal end	20		24		27			28				
		2.0Fr.		2.4Fr.		2.7Fr.			2.8Fr.				
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	100m m	110mm	120mm	
		N	P	Q	R	S		T	U	V	W		
		130m m	140m m	150m m	160m m	170mm		180m m	190m m	200m m	250m m		
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 Y : Standard kit + Y-connector											
12	Specification	(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”). D (For standard kit, the eleventh character is “Z”. In case, guidewire type is double angled.)											
	With a double marker at the catheter tip (if a guide wire is attached)	W (For standard kit, the eleventh character is “Z”. In case, guidewire type is double angled.) V (For standard kit, the eleventh character is “Z”. In case, guidewire type is angled.)											
	Without a marker at the catheter tip (if a guide wire is attached)	Q (For standard kit, the eleventh character is “Z”).											

*: For product w/o guide wire, the 10th character is skipped (the 11th and 12th characters shift 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

<Stepless flexibility type>

M ☐ — ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
1 2 3 4 5 6 7 8 9 10 11

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

*1: When additional character is required for without-GW product

EC Certificate - Full Quality Assurance System

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

No.**CE 554734****Issued To:**

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

In respect of:

The Design and Manufacture of Balloon Dilatation Catheters, PTCA Guidewires, Angiographic Catheters, MicroGuide catheters, Coronary Imaging Catheters and coronary optical coherence tomography system.

Those aspects of Annex II related to securing and maintaining the sterility of the MDU cover, Extension Wires, and related accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-10-30**

Date: **2019-08-12**

Expiry Date: **2024-05-26**

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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 554734

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class III		
---	RyujinPlus	See CE 554735
---	Tazuna	See CE 554735
---	Hiryu	See CE 599214
---	RyujinPlus OTW	See CE 578316
---	Accuforce	See CE 608484
---	Ryurei	See CE 661655
---	Progreat	See CE 580672
---	Finecross MG	See CE 597867
---	Runthrough NS	See CE 613749
---	FastView	See CE 585621

First Issued: **2009-10-30**

Date: **2019-08-12**

Expiry Date: **2024-05-26**

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Page 2 of 3

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 554734

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1202	LUNAWAVE	---
Class Is		
MD 0106	RunthroughNS Extension wire	---
MD 0106	Fast View MDU cover	---

First Issued: **2009-10-30**Date: **2019-08-12**Expiry Date: **2024-05-26**

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Page 3 of 3

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 554734**
Date: **2019-08-12**
Issued To: **Terumo Corporation**
44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
151-0072
Japan

Subcontractor:	Service(s) supplied
SUZUKI Co., Ltd. 2150-1 Ogawara Suzaka-shi Nagano 382-8588 Japan	Manufacture
Terumo Corporation Ashitaka Plant 150, Maimaigi-cho, Fujinomiya City, Shizuoka Prefecture 418-0015 Japan	Design Development ETO Sterilization Manufacture
Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium	EU Representative

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 554734**
 Date: **2019-08-12**
 Issued To: **Terumo Corporation**
44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
151-0072
Japan

Subcontractor:

Service(s) supplied

Ueda Japan Radio Co., Ltd.
 2805-72
 Nagase
 Ueda-shi
 Nagano
 386-0407
 Japan

Manufacture

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 554734**
 Date: **2019-08-12**
 Issued To: **Terumo Corporation**
44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
151-0072
Japan

Date	Reference Number	Action
30 October 2009	7443727	First Issue – Transfer from another Notified Body.
17 September 2010	7560390	Certificate renewal.
23 December 2011	7778290	Addition of "Angiographic Catheters" to the scope of the certificate. Additional service supplied for ETO sterilization at the Terumo Ashitaka Plant.
30 March 2012	7730762	Update to scope of certificate to add Coronary Imaging Catheters.
21 December 2012	7916383	Extension to scope to include LUNAWAVE.
18 April 2013	7948395 7959985	Optical Coherence Tomography System (LUNAWAVE) was introduced under 7916383 in Dec 2012. Brand name 'LUNAWAVE' has now been removed from scope. This does not affect the device types covered by the certificate. Extension of scope to include Class I sterile MDU cover and accessories.
4 June 2013	7974363	Extension to scope to include micro-guide catheters.
4 June 2014	8164373	Certificate renewal.
1 August 2014	8196034	Addition of "PTCA Guidewires" and "sterility of...Extension Wires" to the scope.

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 554734**
Date: **2019-08-12**
Issued To: **Terumo Corporation**
44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
151-0072
Japan

Date	Reference Number	Action
27 April 2018	8942575	Added design and development service to Terumo Ashika Plant subcontractor.
04 March 2019	7778938	Traceable to NB 0086.
Current	9789827	Certificate Renewal. Added products table and subcontractors Ueda Japan Radio and SUZUKI.

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Page 2 of 2

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

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

Scope: Design and Development, Manufacture, Distribution and Service of

- Angiographic Catheter and Accessories
- Anti-adhesion System
- Balloon Dilatation Catheter
- Blood Collection/Transfusion Device and Accessories
- Blood Glucose Monitoring system
- Cartridge Injection System
- Catheter Introducer and Accessories
- Electronic Sphygmomanometer
- Electronic Thermometer
- Embolization Prosthesis and Accessories
- Endoscopic Vessel Harvesting System
- Extracorporeal Circulation Device and Accessories
- Falloposcopic Tuboplasty Device and Accessories
- Guide Wire and Accessories
- Guiding/Micro Catheter and Accessories
- Infusion Pump
- Infusion Set and Accessories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.


Report No.: 150241635-301

Effective date: 2021-08-30

Expiry date: 2023-08-29

Issue date: 2021-08-29




Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1485480-1

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

- Intravascular Imaging Catheter and Accessories
- Intravascular Imaging System and Accessories
- Intravenous Catheter
- Left-Ventricular Assist System
- Needle
- Open-heart surgery devices and Accessories
- Oral Care Device and Accessories
- Peritoneal Dialysis Device and Accessories
- Pneumatically-powered Massager
- Prefillable Syringe
- Pulse Oximeter
- Radial Artery Hemostasis Device and Accessories
- Stent System
- Syringe
- Syringe Infusion Pump
- Syringe with Needle
- Thrombus Removal Device
- Tube Catheter and Accessories
- Urine test strip
- Vascular Closure Device
- Vascular Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

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Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1485480-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Terumo Corporation 44-1, 2-chome, Hatagaya Shibuya-ku, Tokyo 151-0072 Japan	Aspects related to Design and Development, Manufacture, Distribution and Service.
/02	c/o Terumo Corporation - Tokyo office 3-20-2, Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Aspects related to Design and Development and activities related to corporate management processes.
/03	c/o Terumo Corporation, Shonan Center 1500, Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Aspects related to Distribution and activities related to customer communication processes.

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