

Accuforce®

PTCA Dilatation Catheter



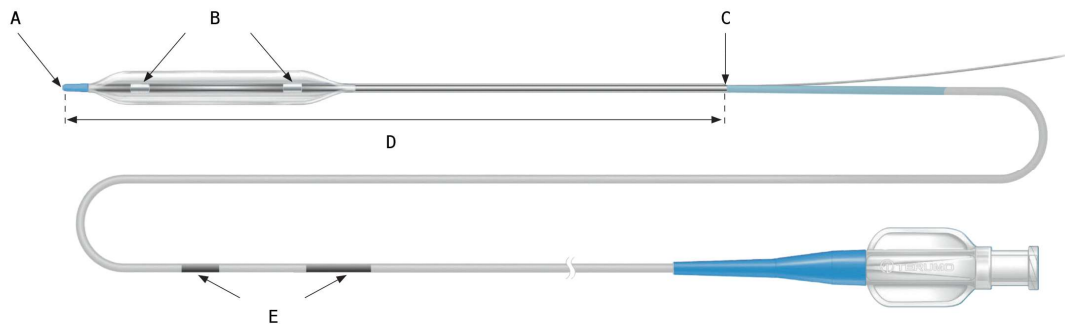
The ideal balance of high pressure and high resistance, accurate dilatation and advanced deliverability, with no compromise on procedural success.

Product Characteristics

- Impressive high pressure resistance up to 22 atm²
- Optimised (re)crossability and deliverability thanks to the reinforced guidewire exit port and low profile shaft ¹
- Improved accuracy of dilatation even in the most challenging cases with shorter balloon shoulders ^{1, 2}

¹ Comparison with Hiryu. Non Compliant PTCA Balloon Catheter manufactured by Terumo Corporation.

² Data on file at Terumo Corporation. Compliance comparison from benchmark tests data vs. Medtronic Inc NC Sprinter™. vs. Abbott NC Trek™. vs. Boston Scientific NC Quantum Apex™. vs. Cordis J&J Empira NCTM and



- A Entry profile 0.43 mm
B Radiopaque marker
C Guidewire port
D If code ends with HW = Hydrophilic coating,
SW = Shaft coating
E Depth marker

General specifications

Balloon Marker	Double
Coating	Hydrophilic
Entry Profile	0.43 mm
Guidewire Compatibility - Maximum Diameter	0.014 in / 0.36 mm
Lesion Entry Profile	0.43 mm
Nominal Pressure	12 atm / 1216 kPa
Shaft Diameter - Distal	0.86 mm / 2.6 Fr
Shaft Diameter - Mid	0.84 mm / 2.5 Fr
Shaft Diameter - Proximal	0.64 mm / 1.9 Fr
Usable Length	145 cm

Item specifications

Balloon Diameter	Balloon Length	Rated Burst Pressure	Code
2 mm	6 mm	22 atm 2229 kPa	DC-RM2006HSW
2 mm	8 mm	22 atm 2229 kPa	DC-RM2008HSW
2 mm	12 mm	22 atm 2229 kPa	DC-RM2012HHW
2 mm	15 mm	22 atm 2229 kPa	DC-RM2015HHW
2 mm	20 mm	22 atm 2229 kPa	DC-RM2020HHW
2.25 mm	6 mm	22 atm 2229 kPa	DC-RM2206HSW
2.25 mm	8 mm	22 atm 2229 kPa	DC-RM2208HSW
2.25 mm	12 mm	22 atm 2229 kPa	DC-RM2212HHW
2.25 mm	15 mm	22 atm 2229 kPa	DC-RM2215HHW
2.25 mm	20 mm	22 atm 2229 kPa	DC-RM2220HHW
2.5 mm	6 mm	22 atm 2229 kPa	DC-RM2506HSW
2.5 mm	8 mm	22 atm 2229 kPa	DC-RM2508HSW
2.5 mm	12 mm	22 atm 2229 kPa	DC-RM2512HHW
2.5 mm	15 mm	22 atm 2229 kPa	DC-RM2515HHW
2.5 mm	20 mm	22 atm 2229 kPa	DC-RM2520HHW
2.5 mm	25 mm	22 atm 2229 kPa	DC-RM2525HHW
2.5 mm	30 mm	22 atm 2229 kPa	DC-RM2530HHW
2.75 mm	6 mm	22 atm 2229 kPa	DC-RM2706HSW
2.75 mm	8 mm	22 atm 2229 kPa	DC-RM2708HSW
2.75 mm	12 mm	22 atm 2229 kPa	DC-RM2712HHW
2.75 mm	15 mm	22 atm 2229 kPa	DC-RM2715HHW
2.75 mm	20 mm	22 atm 2229 kPa	DC-RM2720HHW
3 mm	6 mm	22 atm 2229 kPa	DC-RM3006HSW
3 mm	8 mm	22 atm 2229 kPa	DC-RM3008HSW
3 mm	12 mm	22 atm 2229 kPa	DC-RM3012HHW
3 mm	15 mm	22 atm 2229 kPa	DC-RM3015HHW
3 mm	20 mm	22 atm 2229 kPa	DC-RM3020HHW
3 mm	25 mm	22 atm 2229 kPa	DC-RM3025HHW
3 mm	30 mm	22 atm 2229 kPa	DC-RM3030HHW
3.25 mm	6 mm	22 atm 2229 kPa	DC-RM3206HSW
3.25 mm	8 mm	22 atm 2229 kPa	DC-RM3208HSW
3.25 mm	12 mm	22 atm 2229 kPa	DC-RM3212HHW
3.25 mm	15 mm	22 atm 2229 kPa	DC-RM3215HHW
3.25 mm	20 mm	22 atm 2229 kPa	DC-RM3220HHW
3.5 mm	6 mm	22 atm 2229 kPa	DC-RM3506HSW
3.5 mm	8 mm	22 atm 2229 kPa	DC-RM3508HSW

Please quote above item reference codes when placing an order

Item specifications

Balloon Diameter	Balloon Length	Rated Burst Pressure	Code
3.5 mm	12 mm	22 atm 2229 kPa	DC-RM3512HHW
3.5 mm	15 mm	22 atm 2229 kPa	DC-RM3515HHW
3.5 mm	20 mm	22 atm 2229 kPa	DC-RM3520HHW
3.5 mm	25 mm	22 atm 2229 kPa	DC-RM3525HHW
3.5 mm	30 mm	22 atm 2229 kPa	DC-RM3530HHW
3.75 mm	6 mm	22 atm 2229 kPa	DC-RM3706HSW
3.75 mm	8 mm	22 atm 2229 kPa	DC-RM3708HSW
3.75 mm	12 mm	22 atm 2229 kPa	DC-RM3712HHW
3.75 mm	15 mm	22 atm 2229 kPa	DC-RM3715HHW
3.75 mm	20 mm	22 atm 2229 kPa	DC-RM3720HHW
4 mm	6 mm	22 atm 2229 kPa	DC-RM4006HSW
4 mm	8 mm	22 atm 2229 kPa	DC-RM4008HSW
4 mm	12 mm	22 atm 2229 kPa	DC-RM4012HHW
4 mm	15 mm	22 atm 2229 kPa	DC-RM4015HHW
4 mm	20 mm	22 atm 2229 kPa	DC-RM4020HHW
4.5 mm	6 mm	20 atm 2026 kPa	DC-RM4506HSW
4.5 mm	8 mm	20 atm 2026 kPa	DC-RM4508HSW
4.5 mm	12 mm	20 atm 2026 kPa	DC-RM4512HSW
4.5 mm	15 mm	20 atm 2026 kPa	DC-RM4515HSW
5 mm	6 mm	20 atm 2026 kPa	DC-RM5006HSW
5 mm	8 mm	20 atm 2026 kPa	DC-RM5008HSW
5 mm	12 mm	20 atm 2026 kPa	DC-RM5012HSW
5 mm	15 mm	20 atm 2026 kPa	DC-RM5015HSW

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION

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

being the manufacturer of:

Accuforce

PTCA Balloon Dilatation Catheter

Product : Balloon Dilatation 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 608484) under the supervision of BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, 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, July 30, 2019

(place and date of issue)

A handwritten signature in blue ink, reading "Toshio Nakashima".

Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION



Appendix A - List of Code Number Structure

D C — □ □ □ □ □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Denotation													
1-2	Product	DC: dilatation catheter												
3	Destination	- : for domestic market export												
4	Catheter type	R: rapid exchange type												
5	Type	M:Accuforce												
6-7	Balloon Diameter(mm)	Character	20	22	25	27	30	32	35	37	40	45	50	
		Diameter	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00	
8-9	Balloon length (mm)	Character	06	08	10	12	15	20	25	30				
		Length	6	8	10	12	15	20	25	30				
10	Shaft type	H: hypo tube structure												
11	Hydrophilic coating Type	H: full coating												
		S: shaft coating only												
12	Marker type	None: single marker												
		W : double marker												

Appendix B - List of Product Code

Product code	Specification	
	Balloon diameter	Balloon length
DC- RM 2006HSW	2.00	6
DC- RM 2206HSW	2.25	6
DC- RM 2506HSW	2.50	6
DC- RM 2706HSW	2.75	6
DC- RM 3006HSW	3.00	6
DC- RM 3206HSW	3.25	6
DC- RM 3506HSW	3.50	6
DC- RM 3706HSW	3.75	6
DC- RM 4006HSW	4.00	6
DC- RM 4506HSW	4.50	6
DC- RM 5006HSW	5.00	6
DC- RM 2008HSW	2.00	8
DC- RM 2208HSW	2.25	8
DC- RM 2508HSW	2.50	8
DC- RM 2708HSW	2.75	8
DC- RM 3008HSW	3.00	8
DC- RM 3208HSW	3.25	8
DC- RM 3508HSW	3.50	8
DC- RM 3708HSW	3.75	8
DC- RM 4008HSW	4.00	8
DC- RM 4508HSW	4.50	8
DC- RM 5008HSW	5.00	8
DC- RM 2010HHW	2.00	10
DC- RM 2210HHW	2.25	10
DC- RM 2510HHW	2.50	10
DC- RM 2710HHW	2.75	10
DC- RM 3010HHW	3.00	10
DC- RM 3210HHW	3.25	10
DC- RM 3510HHW	3.50	10
DC- RM 3710HHW	3.75	10
DC- RM 4010HHW	4.00	10
DC- RM 4510HSW	4.50	10
DC- RM 5010HSW	5.00	10
DC- RM 2012HHW	2.00	12
DC- RM 2212HHW	2.25	12
DC- RM 2512HHW	2.50	12
DC- RM 2712HHW	2.75	12
DC- RM 3012HHW	3.00	12
DC- RM 3212HHW	3.25	12
DC- RM 3512HHW	3.50	12
DC- RM 3712HHW	3.75	12
DC- RM 4012HHW	4.00	12
DC- RM 4512HSW	4.50	12
DC- RM 5012HSW	5.00	12

Product code	Specification	
	Balloon diameter	Balloon length
DC- RM 2015HHW	2.00	15
DC- RM 2215HHW	2.25	15
DC- RM 2515HHW	2.50	15
DC- RM 2715HHW	2.75	15
DC- RM 3015HHW	3.00	15
DC- RM 3215HHW	3.25	15
DC- RM 3515HHW	3.50	15
DC- RM 3715HHW	3.75	15
DC- RM 4015HHW	4.00	15
DC- RM 4515HSW	4.50	15
DC- RM 5015HSW	5.00	15
DC- RM 2020HHW	2.00	20
DC- RM 2220HHW	2.25	20
DC- RM 2520HHW	2.50	20
DC- RM 2720HHW	2.75	20
DC- RM 3020HHW	3.00	20
DC- RM 3220HHW	3.25	20
DC- RM 3520HHW	3.50	20
DC- RM 3720HHW	3.75	20
DC- RM 4020HHW	4.00	20
DC- RM 2525HHW	2.50	25
DC- RM 2725HHW	2.75	25
DC- RM 3025HHW	3.00	25
DC- RM 3225HHW	3.25	25
DC- RM 3525HHW	3.50	25
DC- RM 2530HHW	2.50	30
DC- RM 2730HHW	2.75	30
DC- RM 3030HHW	3.00	30
DC- RM 3230HHW	3.25	30
DC- RM 3530HHW	3.50	30

EC Design-Examination Certificate

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

No.**CE 608484****Issued To:**

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

In respect of:

Accuforce PTCA balloon dilatation catheter

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-07-31**

Date: **2019-07-26**

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

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Page 1 of 12

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 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.

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Supplementary Information to CE 608484

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151-0072
Japan

Product coding system is as follows:

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

Character number	Denotation									
1-2	Product		DC: dilatation catheter							
3	Destination		-: for Japanese market / export							
4	Catheter type		R: rapid exchange type							
5	Type		M: Accuforce							
6-7	Balloon diameter (mm)	Character	20	22	25	27	30	32		
		Diameter	2.00	2.25	2.50	2.75	3.00	3.25		
		Character	35	37	40	45	50			
		Diameter	3.50	3.75	4.00	4.50	5.00			
8-9	Balloon length (mm)	Character Length	06, 6,	08, 8,	10, 10,	12, 12,	15, 15,	20, 20,	25, 25,	30, 30,
10	Shaft type		H: Hypo tube structure							
11	Hydrophilic coating type		H: full coating S: shaft coating only							
12	Marker type		None: single marker W: double marker							

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Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2006HSW	2.00	6
DC- RM 2206HSW	2.25	6
DC- RM 2506HSW	2.50	6
DC- RM 2706HSW	2.75	6
DC- RM 3006HSW	3.00	6
DC- RM 3206HSW	3.25	6
DC- RM 3506HSW	3.50	6
DC- RM 3706HSW	3.75	6
DC- RM 4006HSW	4.00	6
DC- RM 4506HSW	4.50	6
DC- RM 5006HSW	5.00	6

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Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2008HSW	2.00	8
DC- RM 2208HSW	2.25	8
DC- RM 2508HSW	2.50	8
DC- RM 2708HSW	2.75	8
DC- RM 3008HSW	3.00	8
DC- RM 3208HSW	3.25	8
DC- RM 3508HSW	3.50	8
DC- RM 3708HSW	3.75	8
DC- RM 4008HSW	4.00	8
DC- RM 4508HSW	4.50	8
DC- RM 5008HSW	5.00	8

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Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2010HHW	2.00	10
DC- RM 2210HHW	2.25	10
DC- RM 2510HHW	2.50	10
DC- RM 2710HHW	2.75	10
DC- RM 3010HHW	3.00	10
DC- RM 3210HHW	3.25	10
DC- RM 3510HHW	3.50	10
DC- RM 3710HHW	3.75	10
DC- RM 4010HHW	4.00	10
DC- RM 4510HSW	4.50	10
DC- RM 5010HSW	5.00	10

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Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2012HHW	2.00	12
DC- RM 2212HHW	2.25	12
DC- RM 2512HHW	2.50	12
DC- RM 2712HHW	2.75	12
DC- RM 3012HHW	3.00	12
DC- RM 3212HHW	3.25	12
DC- RM 3512HHW	3.50	12
DC- RM 3712HHW	3.75	12
DC- RM 4012HHW	4.00	12
DC- RM 4512HSW	4.50	12
DC- RM 5012HSW	5.00	12

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Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2015HHW	2.00	15
DC- RM 2215HHW	2.25	15
DC- RM 2515HHW	2.50	15
DC- RM 2715HHW	2.75	15
DC- RM 3015HHW	3.00	15
DC- RM 3215HHW	3.25	15
DC- RM 3515HHW	3.50	15
DC- RM 3715HHW	3.75	15
DC- RM 4015HHW	4.00	15
DC- RM 4515HSW	4.50	15
DC- RM 5015HSW	5.00	15

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Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2020HHW	2.00	20
DC- RM 2220HHW	2.25	20
DC- RM 2520HHW	2.50	20
DC- RM 2720HHW	2.75	20
DC- RM 3020HHW	3.00	20
DC- RM 3220HHW	3.25	20
DC- RM 3520HHW	3.50	20
DC- RM 3720HHW	3.75	20
DC- RM 4020HHW	4.00	20

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Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2525HHW	2.50	25
DC- RM 2725HHW	2.75	25
DC- RM 3025HHW	3.00	25
DC- RM 3225HHW	3.25	25
DC- RM 3525HHW	3.50	25

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Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2530HHW	2.50	30
DC- RM 2730HHW	2.75	30
DC- RM 3030HHW	3.00	30
DC- RM 3230HHW	3.25	30
DC- RM 3530HHW	3.50	30

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Certificate History

Date	Reference Number	Action
31 July 2014	10144839	First Issue.
16 March 2016	10159714	Change affecting Tyvek® 1073B and Tyvek® 1059B packaging materials- all product codes are affected.
08 August 2018	8917152	Adding an alternative adhesive type to existing adhesive bond between shaft tube (outer tube, proximal) and Hub.
09 November 2018	8873289	Using an additional sterilization chamber as part of the existing sterilization facility (Ashitaka). Correction of typographical error in certificate scope and supplementary information - changed "dilation" to "dilatation".
04 March 2019	7778938	Traceable to NB 0086.

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151-0072
Japan

Date	Reference Number	Action
Current	9716645	Certificate renewal. Removal of product codes DC- RM 1206HH, DC- RM 1506HH, DC- RM 1208HH, DC- RM 1508HH, DC- RM 1210HH, DC- RM 1510HH, DC- RM 1515HH, DC- RM 1520HH, DC- RM 2025HHW, DC- RM 2225HHW, DC- RM 3725HHW, DC- RM 4025HHW, DC- RM 2030HHW, DC- RM 2230HHW, DC- RM 3730HHW, DC- RM 4030HHW, DC- RM 2235HHW, DC- RM 2535HHW, DC- RM 2735HHW, DC- RM 3035HHW, DC- RM 3535HHW, DC- RM 4035HHW.

First Issued: **2014-07-31**Date: **2019-07-26**Expiry Date: **2024-05-26**

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Page 12 of 12

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 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

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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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

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

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

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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

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

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29



Michiaki Aihara
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

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.

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29



Michiaki Aihara

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