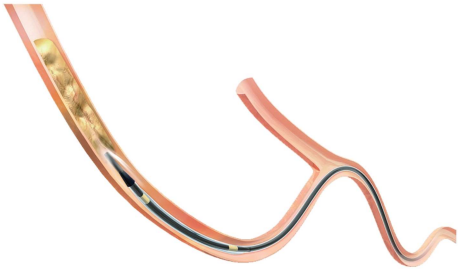
Ryujin™ Plus RX



PTCA Dilatation Catheter

Ryujin™ Plus rapid exchange balloon catheter is intended for use during percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.

This device is designed for crossing routine lesions without compromising trackability.

Product Characteristics

- *145 cm-long shaft model is suitable for CART technique (Controlled Antegrade and Retrograde subintimal Tracking)*
- *Stiff plastic shaft designed towards excellent kink resistance*
- *Inner shaft material designed towards smooth guidewire handling*
- *Durable hydrophilic coating*

A Ø 1.25 & 1,5 mm has 1 marker, Others have 2 radiopaque markers
B Distal shaft: 2.4 Fr (0.80 mm) For Ø 1.25 to 2 mm, 2.5 Fr (0.84 mm) For Ø 2.25 to 3 mm, 2.6 Fr (0.87 mm) For Ø 3.25 to 4 mm
C Proximal shaft: 2 Fr (0.67 mm)
D Entry profile
E Depth markers

General specifications

Coating	Hydrophilic
Entry Profile - Diameter	0.43 mm
Guidewire Compatibility - Maximum Diameter	0,014 in / 0,36 mm
Nominal Pressure	6 atm / 608 kPa
Shaft Diameter - Proximal	0.67 mm / 2 Fr
Usable Length	145 cm

IS803/70GB1219KAIV

Item specifications

Balloon Diameter	Balloon Length	Shaft Diameter - Distal	Rated Burst Pressure	Code
1.25	10 mm	2.4 Fr 0.80 mm	14 atm 1419 kPa	DC-RH1210EH
1.25	15 mm	2.4 Fr 0.80 mm	14 atm 1419 kPa	DC-RH1215EH
1.5	15 mm	2.4 Fr 0.80 mm	14 atm 1419 kPa	DC-RH1515EH
1.5	20 mm	2.4 Fr 0.80 mm	14 atm 1419 kPa	DC-RH1520EH
2	15 mm	2.4 Fr 0.80 mm	14 atm 1419 kPa	DC-RH2015EHW
2	20 mm	2.4 Fr 0.80 mm	14 atm 1419 kPa	DC-RH2020EHW
2	30 mm	2.4 Fr 0.80 mm	14 atm 1419 kPa	DC-RH2030EHW
2	40 mm	2.4 Fr 0.80 mm	14 atm 1419 kPa	DC-RH2040EHW
2.25	10 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2210EHW
2.25	15 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2215EHW
2.25	20 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2220EHW
2.25	30 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2230EHW
2.25	40 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2240EHW
2.5	10 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2510EHW
2.5	15 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2515EHW
2.5	20 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2520EHW
2.5	30 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2530EHW
2.5	40 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2540EHW
2.75	10 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2710EHW
2.75	15 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2715EHW
2.75	20 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2720EHW
2.75	30 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2730EHW
2.75	40 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH2740EHW
3	10 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH3010EHW
3	15 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH3015EHW
3	20 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH3020EHW
3	30 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH3030EHW
3	40 mm	2.5 Fr 0.83 mm	14 atm 1419 kPa	DC-RH3040EHW
3.25	10 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3210EHW
3.25	15 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3215EHW
3.25	20 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3220EHW
3.25	30 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3230EHW
3.5	10 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3510EHW
3.5	15 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3515EHW
3.5	20 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3520EHW
3.5	30 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3530EHW

Please quote above item reference codes when placing an order

IS803/70GB1219K4IV

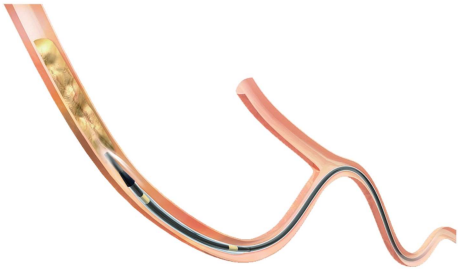
Item specifications

Balloon Diameter	Balloon Length	Shaft Diameter - Distal	Rated Burst Pressure	Code
3.5	40 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3540EHW
3.75	15 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3715EHW
3.75	20 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH3720EHW
4	10 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH4010EHW
4	15 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH4015EHW
4	20 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH4020EHW
4	30 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH4030EHW
4	40 mm	2.6 Fr 0.87 mm	12 atm 1216 kPa	DC-RH4040EHW

Please quote above item reference codes when placing an order

IS803/70GB1219IKAIV

Ryujin™ Plus OTW

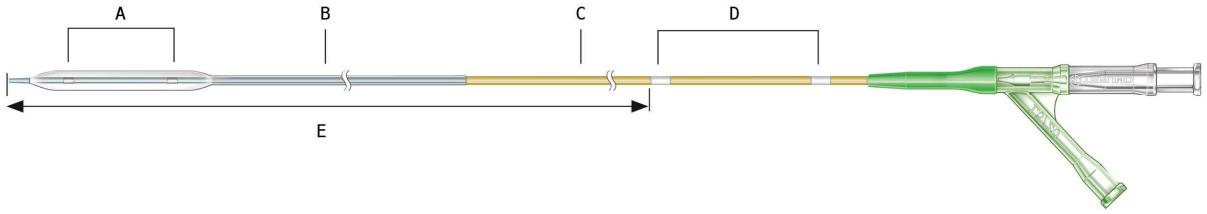


PTCA Dilatation Catheter

Ryujin™ Plus OTW is intended for use during percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.
Ryujin™ Plus OTW is a PTCA balloon dilatation catheter with a coaxial system utilizing innovative Ryujin technologies. Long shaft model (usable catheter length: 148 cm) makes it possible to reach very distal lesions.

Product Characteristics

- *148 cm-long shaft model is suitable for CART technique (Controlled Antegrade and Retrograde subintimal Tracking)*
- *Stiff plastic shaft designed towards excellent kink resistance*
- *Inner shaft material designed towards smooth guidewire handling*
- *Durable hydrophilic coating*



A Markers at Ø 1.25 and 1,5 mm
B Distal shaft: 2.5 Fr (0.83 mm), 2.7 Fr (0.90 mm)
C Proximal shaft: 3.2 Fr (1.07 mm)
D Depth markers
E Hydrophilic coating

General specifications

Entry Profile - Diameter	0.43 mm
Guidewire Compatibility - Maximum Diameter	0.014 in / 0.36 mm
Nominal Pressure	6 atm / 608, 698 kPa
Shaft Diameter - Proximal	1.07 mm / 3.2 Fr

IS803/43GB1219KAIII

Item specifications

Balloon Diameter	Balloon Length	Usable Length	Shaft Diameter - Distal	Rated Burst Pressure	Coating	Code
1.25 mm	10 mm	135 cm	2.5 Fr 0.83 mm	14 atm 1419 kPa	Hydrophilic Silicone	DC-PH1210PH
1.25 mm	10 mm	148 cm	2.5 Fr 0.83 mm	14 atm 1419 kPa	Hydrophilic Silicone	DC-PH1210LH
1.25 mm	20 mm	148 cm	2.5 Fr 0.83 mm	14 atm 1419 kPa	Hydrophilic Silicone	DC-PH1220LH
1.5 mm	15 mm	135 cm	2.5 Fr 0.83 mm	14 atm 1419 kPa	Hydrophilic Silicone	DC-PH1515PH
2 mm	20 mm	135 cm	2.5 Fr 0.83 mm	14 atm 1419 kPa	Hydrophilic Silicone	DC-PH2020PHW
2 mm	20 mm	148 cm	2.5 Fr 0.83 mm	14 atm 1419 kPa	Hydrophilic Silicone	DC-PH2020LHW
2.5 mm	20 mm	135 cm	2.7 Fr 0.9 mm	14 atm 1419 kPa	Hydrophilic Silicone	DC-PH2520PHW
2.5 mm	20 mm	148 cm	2.7 Fr 0.9 mm	14 atm 1419 kPa	Hydrophilic Silicone	DC-PH2520LHW
3 mm	20 mm	135 cm	2.7 Fr 0.9 mm	14 atm 1419 kPa	Hydrophilic Silicone	DC-PH3020PHW
3.5 mm	20 mm	135 cm	2.7 Fr 0.9 mm	12 atm 1216 kPa	Hydrophilic Silicone	DC-PH3520PHW

Please quote above item reference codes when placing an order

IS803/43GB1219KAIII

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 554735**

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

In respect of:

PTCA Balloon Dilatation 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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-10-30** Date: **2019-10-04** Expiry Date: **2024-05-26**

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Supplementary Information to CE 554735

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RyujinPlus Product Code

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 export/domestic use								
4	Catheter type	**R**: rapid exchange type								
5	Type	**H**: Ryujin Plus								
6-7	Balloon diameter (mm)	Character	**12**	**15**	**20**	**22**	**25**	**27**	**30**	**32**
		Diameter	1.25	1.5	2.0	2.25	2.5	2.75	3.0	3.25
		Character	**35**	**37**	**40**					
		Diameter	3.5	3.75	4.0					
8-9	Balloon length (mm)	Character	**10**	**15**	**20**	**30**	**40**			
		Length	10	15	20	30	40			
10	Shaft type	**E**: PTFE coating shaft								
11	Hydrophilic coating type	**H**: full coating								
12	Marker type	**Blank**: single marker, **W**: double marker								

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Catalogue Number	Device Name	Model, Type		Intended purpose per IFU	Classification
		Balloon diameter (mm)	Balloon length (mm)		
DC-RH1210EH	Ryujin Plus	1.25	10	The Ryujin Plus ("dilatation catheter") is intended to be used for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.	Class III
DC-RH2210EHW		2.25	10		
DC-RH2510EHW		2.50	10		
DC-RH2710EHW		2.75	10		
DC-RH3010EHW		3.00	10		
DC-RH3210EHW		3.25	10		
DC-RH3510EHW		3.50	10		
DC-RH4010EHW		4.00	10		
DC-RH1215EH		1.25	15		
DC-RH1515EH		1.50	15		
DC-RH2015EHW		2.00	15		
DC-RH2215EHW		2.25	15		
DC-RH2515EHW		2.50	15		
DC-RH2715EHW		2.75	15		

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Catalogue Number	Device Name	Model, Type		Intended purpose per IFU	Classification
		Balloon diameter (mm)	Balloon length (mm)		
DC-RH3015EHW	Ryujin Plus	3.00	15	The Ryujin Plus ("dilatation catheter") is intended to be used for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.	Class III
DC-RH3215EHW		3.25	15		
DC-RH3515EHW		3.50	15		
DC-RH3715EHW		3.75	15		
DC-RH4015EHW		4.00	15		
DC-RH1520EH		1.50	20		
DC-RH2020EHW		2.00	20		
DC-RH2220EHW		2.25	20		
DC-RH2520EHW		2.50	20		
DC-RH2720EHW		2.75	20		
DC-RH3020EHW		3.00	20		
DC-RH3220EHW		3.25	20		
DC-RH3520EHW		3.50	20		
DC-RH3720EHW		3.75	20		

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Catalogue Number	Device Name	Model, Type		Intended purpose per IFU	Classification
		Balloon diameter (mm)	Balloon length (mm)		
DC-RH4020EHW	Ryujin Plus	4.00	20	The Ryujin Plus ("dilatation catheter") is intended to be used for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.	Class III
DC-RH2030EHW		2.00	30		
DC-RH2230EHW		2.25	30		
DC-RH2530EHW		2.50	30		
DC-RH2730EHW		2.75	30		
DC-RH3030EHW		3.00	30		
DC-RH3230EHW		3.25	30		
DC-RH3530EHW		3.50	30		
DC-RH4030EHW		4.00	30		
DC-RH2040EHW		2.00	40		
DC-RH2240EHW		2.25	40		
DC-RH2540EHW		2.50	40		
DC-RH2740EHW		2.75	40		
DC-RH3040EHW		3.00	40		
DC-RH3540EHW		3.50	40		
DC-RH4040EHW		4.00	40		

First Issued: **2009-10-30** Date: **2019-10-04** Expiry Date: **2024-05-26**

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Supplementary Information to CE 554735

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Tazuna Product Code System

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 export/domestic use							
4	Catheter type	**R**: rapid exchange type							
5	Type	**K**: Tazuna							
6-7	Balloon diameter (mm)	Character	**12**	**15**	**20**	**22**	**25**	**27**	**30**
		Diameter	1.25	1.5	2.0	2.25	2.5	2.75	3.0
8-9	Balloon length (mm)	Character	**10**	**15**	**20**				
		Length	10	15	20				
10	Shaft type	**E**: PTFE coating shaft							
11	Hydrophilic coating type	**H**: full coating							
12	Marker type	**Blank**: single marker, **W**: double marker							

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Catalogue Number	Device Name	Model, Type		Intended purpose per IFU	Classification
		Balloon diameter (mm)	Balloon length (mm)		
DC-RK1210EH	Tazuna	1.25	10	The Tazuna ("dilatation catheter") is intended to be used for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.	Class III
DC-RK1510EH		1.50	10		
DC-RK2010EH		2.00	10		
DC-RK2210EH		2.25	10		
DC-RK2510EHW		2.50	10		
DC-RK3010EHW		3.00	10		
DC-RK1215EH		1.25	15		
DC-RK1515EH		1.50	15		
DC-RK2015EHW		2.00	15		
DC-RK2215EHW		2.25	15		
DC-RK2515EHW		2.50	15		
DC-RK2715EHW		2.75	15		
DC-RK3015EHW		3.00	15		
DC-RK2020EHW		2.00	20		

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Catalogue Number	Device Name	Model, Type		Intended purpose per IFU	Classification
		Balloon diameter (mm)	Balloon length (mm)		
DC-RK2220EHW	Tazuna	2.25	20	The Tazuna ("dilatation catheter") is intended to be used for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.	Class III
DC-RK2520EHW		2.50	20		
DC-RK2720EHW		2.75	20		
DC-RK3020EHW		3.00	20		

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Certificate History

Date	Reference Number	Action
30 October 2009	10109826	First issue - Transfer from another Notified Body.
30 October 2009	10109889	Addition of the Tazuna Balloon Dilatation Catheter Line Extension.
03 August 2011	10125153	Change of sterilization unit for Ryujin Plus and Tazuna products.
20 October 2014	10150693	Certificate renewal.
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 previous change reference number to 8917152.
04 March 2019	7778938	Traceable to NB 0086.
Current	9759539	Certificate renewal. Administrative update to product table format Removed balloon lengths 30 and 40mm for Tazuna catheter

First Issued: **2009-10-30** Date: **2019-10-04** Expiry Date: **2024-05-26**

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TERUMO

No. DOC-DQ010-0780
Rev.12

DECLARATION OF CONFORMITY

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

being the manufacturer of:

Ryujin Plus

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 554735) 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, October 25, 2019
(place and date of issue)

Toshio Nakashima
Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

TERUMO

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 export / domestic use							
4	Catheter type	**R**: rapid exchange type							
5	Type	**H**:Ryujin Plus							
6-7	Balloon Diameter(mm)	Character	**12**	**15**	**20**	**22**	**25**	**27**	**30**
		Diameter	1.25	1.5	2.0	2.25	2.5	2.75	3.0
		Character	**32**	**35**	**37**	**40**			
		Diameter	3.25	3.5	3.75	4.0			
8-9	Balloon length (mm)	Character	**10**	**15**	**20**	**30**	**40**		
		Length	10	15	20	30	40		
10	Shaft type	E: PTFE coating shaft							
11	Hydrophilic coating type	H: full coating							
12	Marker type	Blank: single marker, W: double marker							

TERUMO

Appendix B - List of Product Code

Product code	Specification	
	Balloon diameter(mm)	Balloon length(mm)
DC-RH1210EH	1.25	10
DC-RH2210EHW	2.25	10
DC-RH2510EHW	2.50	10
DC-RH2710EHW	2.75	10
DC-RH3010EHW	3.00	10
DC-RH3210EHW	3.25	10
DC-RH3510EHW	3.50	10
DC-RH4010EHW	4.00	10
DC-RH1215EH	1.25	15
DC-RH1515EH	1.50	15
DC-RH2015EHW	2.00	15
DC-RH2215EHW	2.25	15
DC-RH2515EHW	2.50	15
DC-RH2715EHW	2.75	15
DC-RH3015EHW	3.00	15
DC-RH3215EHW	3.25	15
DC-RH3515EHW	3.50	15
DC-RH3715EHW	3.75	15
DC-RH4015EHW	4.00	15
DC-RH1520EH	1.50	20
DC-RH2020EHW	2.00	20
DC-RH2220EHW	2.25	20
DC-RH2520EHW	2.50	20
DC-RH2720EHW	2.75	20
DC-RH3020EHW	3.00	20
DC-RH3220EHW	3.25	20
DC-RH3520EHW	3.50	20
DC-RH3720EHW	3.75	20
DC-RH4020EHW	4.00	20
DC-RH2030EHW	2.00	30
DC-RH2230EHW	2.25	30
DC-RH2530EHW	2.50	30
DC-RH2730EHW	2.75	30
DC-RH3030EHW	3.00	30
DC-RH3230EHW	3.25	30
DC-RH3530EHW	3.50	30
DC-RH4030EHW	4.00	30
DC-RH2040EHW	2.00	40
DC-RH2240EHW	2.25	40
DC-RH2540EHW	2.50	40
DC-RH2740EHW	2.75	40
DC-RH3040EHW	3.00	40
DC-RH3540EHW	3.50	40
DC-RH4040EHW	4.00	40

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**
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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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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**

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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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.

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.

Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

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

Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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

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

Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02