



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

Gay C Stade

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

RyujinPlus Product Code

	C	_	_	_	_	_	_	_	10		47
_1	2	3	4	5	6	7	8	9	10	11	12

Character Number	4 5	Denotation								
1-2	Product		D	C: dilat	ation c	atheter			45	16-5
3	Destination		-	: for ex	port/do	omestic	use	3 0	450	(OX
4	Catheter type		R	rapid e	exchan	ge type				
5	Туре		F	: Ryuji	n Plus				11	
6-7	Balloon	Character	12	15	20	22	25	27	30	32
	diameter (mm)	Diameter	1.25	1.5	2.0	2.25	2.5	2.75	3.0	3.25
		Character	35	37	40			Va	-	
		Diameter	3.5	3.75	4.0					
8-9	Balloon length	Character	10	15	20	30	40	160		
	(mm)	Length	10	15	20	30	40			
10	Shaft type	Shaft type E : PTFE coating shaft								
11	Hydrophilic coati	Hydrophilic coating type H : full coating								
12	Marker type		В	lank: s	ingle n	narker,	W : dou	ıble ma	rker	

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Catalogue	Device	Mode	l, Type	Intended purpose per	100
Number	Name	Balloon diameter (mm)	Balloon length (mm)	IFU	Classification
DC-RH1210EH	Ryujin Plus	1.25	10	The Ryujin Plus	Class III
DC-RH2210EHW		2.25	10	("dilatation catheter") is intended to be used for	
DC-RH2510EHW		2.50	10	percutaneous transluminal	
DC-RH2710EHW		2.75	10	coronary angioplasty (PTCA) for the purpose of improving myocardial	
DC-RH3010EHW		3.00	10		
DC-RH3210EHW		3.25	10	blood flow in the localized stenotic lesion of the	
DC-RH3510EHW		3.50	10	coronary arteries.	
DC-RH4010EHW		4.00	10		
DC-RH1215EH	1	1.25	15	7 4 300	
DC-RH1515EH		1.50	15	9	
DC-RH2015EHW		2.00	15	1100	QI
DC-RH2215EHW		2.25	15	ESS	EM
DC-RH2515EHW		2.50	15		
DC-RH2715EHW		2.75	15		

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		Mode	l, Type		A CASE	
Catalogue Number	Device Name	Balloon diameter (mm)	Balloon length (mm)	Intended purpose per IFU	Classification	
DC-RH3015EHW	Ryujin Plus	3.00	15	The Ryujin Plus	Class III	
DC-RH3215EHW		3.25	15	("dilatation catheter") is intended to be used for		
DC-RH3515EHW		3.50	15	percutaneous		
DC-RH3715EHW		3.75	15	transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic		
DC-RH4015EHW		4.00	15			
DC-RH1520EH		1.50	20			
DC-RH2020EHW		2.00	20	lesion of the coronary		
DC-RH2220EHW		2.25	20	arteries.		
DC-RH2520EHW		2.50	20			
DC-RH2720EHW		2.75	20	7-4/1		
DC-RH3020EHW		3.00	20	A SESS	EBRU	
DC-RH3220EHW		3.25	20	Canal D	h- 39	
DC-RH3520EHW		3.50	20			
DC-RH3720EHW		3.75	20			

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Catalagus	Davies	Model	, Type	- AND 18	All det	
Catalogue Number	Device Name	Balloon diameter (mm)	Balloon length (mm)	Intended purpose per IFU	Classification	
DC-RH4020EHW	Ryujin Plus	4.00	20	The Ryujin Plus ("dilatation	Class III	
DC-RH2030EHW		2.00	30	catheter") is intended to	(12 × 12 ×	
DC-RH2230EHW		2.25	30	be used for percutaneous transluminal coronary		
DC-RH2530EHW		2.50	30	angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic		
DC-RH2730EHW	_	2.75	30			
DC-RH3030EHW		3.00	30			
DC-RH3230EHW		3.25	30	lesion of the coronary		
DC-RH3530EHW		3.50	30	arteries.		
DC-RH4030EHW		4.00	30			
DC-RH2040EHW		2.00	40	7 9 70	2 (0)	
DC-RH2240EHW		2.25	40	7-9/1		
DC-RH2540EHW		2.50	40	11100	RRIV	
DC-RH2740EHW		2.75	40	ESS	ED	
DC-RH3040EHW		3.00	40			
DC-RH3540EHW		3.50	40			
DC-RH4040EHW		4.00	40			

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Supplementary Information to CE 554735

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Tazuna Product Code System

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

Character Number	_		De	notati	on J	178		P	
1-2	Product	Product DC: dilatation catheter							
3	Destination		-	: for ex	cport/do	omestic	use	3 9	25
4	Catheter type		R:	rapid	exchan	ge type			
5	Туре		K	: Tazu	na				16
6-7	Balloon	Character	12	15	20	22	25	27	30
	diameter (mm)	Diameter	1.25	1.5	2.0	2.25	2.5	2.75	3.0
8-9	Balloon length	Character	10	15	20			Va	
	(mm)	Length	10	15	20				
10	Shaft type	Shaft type E : PTFE coating shaft							
11	Hydrophilic coati	Hydrophilic coating type H : full coating							
12	Marker type		В	lank:	single m	narker, '	W : dou	ıble ma	rker

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		Model	, Туре		12 12	
Catalogue Number	Device Name	Balloon diameter (mm)	Balloon length (mm)	Intended purpose per IFU	Classification	
DC-RK1210EH	Tazuna	1.25	10	The Tazuna ("dilatation	Class III	
DC-RK1510EH		1.50	10	catheter") is intended to be used for percutaneous	(ALC) 87	
DC-RK2010EH		2.00	10	transluminal coronary		
DC-RK2210EH		2.25	10	angioplasty (PTCA) for the purpose of improving myocardial blood flow in the		
DC-RK2510EHW		2.50	10			
DC-RK3010EHW		3.00	10	localized stenotic lesion of the coronary arteries.	38	
DC-RK1215EH		1.25	15		Dala	
DC-RK1515EH		1.50	15			
DC-RK2015EHW		2.00	15	7 4 5	5 10	
DC-RK2215EHW		2.25	15	9-9/1		
DC-RK2515EHW		2.50	15	1/100-	QI	
DC-RK2715EHW		2.75	15	35	SE	
DC-RK3015EHW		3.00	15			
DC-RK2020EHW		2.00	20			

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		Mode	l, Type		47/6	
Catalogue Number	Device Name	Balloon diameter (mm)	Balloon length (mm)	Intended purpose per IFU	Classification	
DC-RK2220EHW	Tazuna	2.25	20	The Tazuna ("dilatation	Class III	
DC-RK2520EHW		2.50	20	catheter") is intended to be used for	Children of the Control of the Contr	
DC-RK2720EHW		2.75	20	percutaneous		
DC-RK3020EHW		3.00	20	transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.		

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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

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