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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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		

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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

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