

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

General Manager

Quality Assurance Department

TERUMO CORPORATION



Appendix A - List of Code Number Structure

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 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								



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