

# 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 dilation 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 0086):



Gary Fenton, Global Assurance Director

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

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.

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

**Terumo Corporation**  
**44-1, 2-chome**  
**Hatagaya**  
**Shibuya-ku**  
**Tokyo**  
**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		<b>DC:</b> dilation catheter								
3	Destination		-: for Japanese market / export								
4	Catheter type		<b>R:</b> rapid exchange type								
5	Type		<b>M:</b> Accuforce								
6-7	Balloon diameter (mm)	Character	<b>12</b>	<b>15</b>	<b>20</b>	<b>22</b>	<b>25</b>	<b>27</b>	<b>30</b>	<b>32</b>	
		Diameter	1.25	1.50	2.00	2.25	2.50	2.75	3.00	3.25	
		Character	<b>35</b>	<b>37</b>	<b>40</b>	<b>45</b>	<b>50</b>				
		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,	35, 35mm
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									

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

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

Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 1206HH	1.25	6
DC- RM 1506HH	1.50	6
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

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

Page 3 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.

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

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

Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 1208HH	1.25	8
DC- RM 1508HH	1.50	8
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

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

Page 4 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.

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

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

Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 1210HH	1.25	10
DC- RM 1510HH	1.50	10
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

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

Page 5 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.

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

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

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

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

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

Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 1515HH	1.50	15
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

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

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

Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 1520HH	1.50	20
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

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

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

Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2025HHW	2.00	25
DC- RM 2225HHW	2.25	25
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 3725HHW	3.75	25
DC- RM 4025HHW	4.00	25

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

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

Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2030HHW	2.00	30
DC- RM 2230HHW	2.25	30
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
DC- RM 3730HHW	3.75	30
DC- RM 4030HHW	4.00	30

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

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

Product Code	Specification	
	Balloon Diameter	Balloon Length
DC- RM 2235HHW	2.25	35
DC- RM 2535HHW	2.50	35
DC- RM 2735HHW	2.75	35
DC- RM 3035HHW	3.00	35
DC- RM 3535HHW	3.50	35
DC- RM 4035HHW	4.00	35

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

Page 11 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.

# EC Design-Examination Certificate

## Supplementary Information to CE 608484

Issued To:

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

## Certificate History

Date	Reference Number	Action
31 July 2014	10144839	First Issue

First Issued: **31 July 2014**

Date: **31 July 2014**

Expiry Date: **30 July 2019**

...making excellence a habit.™

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.