

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 736806 R000

**Manufacturer:** Terumo Corporation

**Address:**

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

**Single Registration Number:** JP-MF-000017478

**EU Authorised Representative:** Terumo Europe N.V.

**Address:**

Interleuvenlaan 40  
3001 Leuven  
Belgium

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



First Issue Date: **2022-12-02**

Current Issue Date: **2023-04-19**

Starting Validity Date: **2023-04-19**

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### Device Schedule:

**Device Name:** Progreat

### Intended Purpose as per the Instructions for Use:

This micro catheter is intended for the infusion of contrast media into all blood vessels. The catheter is also intended for drug infusion in intra-arterial therapy and for the infusion of embolic materials for hemostasis. Do not use this product in coronary and cerebral blood vessels.

**Risk Classification:** Class III

**Type** (as per (EU) 2017/2185): MDN 1202

**Basic UDI-DI:** 498735026MCPGMX

Model	With (Y) Without (N) Guide wire	Catheter tip OD	Usable length of catheter	Tip shape of catheter	Protruding length of guide wire	Tip shape of Guide wire
MC-PC2011	N	2.0 Fr	110 cm	Straight	-	-
MC-PC2011Y	N	2.0 Fr	110 cm	Straight	-	-
MC-PC2013	N	2.0 Fr	130 cm	Straight	-	-
MC-PC2015	N	2.0 Fr	150 cm	Straight	-	-
MC-PB2413	N	2.4 Fr	130 cm	Straight	-	-
MC-PC2411	N	2.4 Fr	110 cm	Straight	-	-
MC-PC2413	N	2.4 Fr	130 cm	Straight	-	-
MC-PC2415	N	2.4 Fr	150 cm	Straight	-	-
MC-PV2415Y	N	2.4 Fr	150 cm	Straight	-	-
MC-PC2713	N	2.7 Fr	130 cm	Straight	-	-
MC-PC2715	N	2.7 Fr	150 cm	Straight	-	-
MC-PC2813	N	2.8 Fr	130 cm	Straight	-	-
MC-PV2815Y	N	2.8 Fr	150 cm	Straight	-	-

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Model	With (Y) Without (N) Guide wire	Catheter tip OD	Usable length of catheter	Tip shape of catheter	Protruding length of guide wire	Tip shape of Guide wire
MC-PC2013ZKA	N	2.0 Fr	130 cm	Angled	-	-
MC-PC2013ZKC	N	2.0 Fr	130 cm	J Curve	-	-
MC-PC2015ZKA	N	2.0 Fr	150 cm	Angled	-	-
MC-PC2015ZKC	N	2.0 Fr	150 cm	J Curve	-	-
MC-PC2413ZKA	N	2.4 Fr	130 cm	Angled	-	-
MC-PC2413ZKC	N	2.4 Fr	130 cm	J Curve	-	-
MC-PB2413ZKA	N	2.4 Fr	130 cm	Angled	-	-
MC-PB2413ZKC	N	2.4 Fr	130 cm	J Curve	-	-
MC-PC2415ZKA	N	2.4 Fr	150 cm	Angled	-	-
MC-PC2415ZKC	N	2.4 Fr	150 cm	J Curve	-	-
MC-PV2415ZKA	N	2.4 Fr	150 cm	Angled	-	-
MC-PV2415ZKC	N	2.4 Fr	150 cm	J Curve	-	-
MC-PP24111ZB	Y (0.018")	2.4 Fr	110 cm	Straight	100mm	Angled Pre-shaped
MC-PP24111ZD	Y (0.018")	2.4 Fr	110 cm	Straight	100mm	Double Angled Pre-shaped
MC-PP24131ZB	Y (0.018")	2.4 Fr	130 cm	Straight	100mm	Angled Pre-shaped
MC-PP24131ZD	Y (0.018")	2.4 Fr	130 cm	Straight	100mm	Double Angled Pre-shaped
MC-PP24151ZV	Y (0.018")	2.4 Fr	150 cm	Straight	100mm	Angled Pre-shaped
MC-PP24151ZW	Y (0.018")	2.4 Fr	150 cm	Straight	100mm	Double Angled Pre-shaped
MC-PP27111	Y (0.021")	2.7 Fr	110 cm	Straight	100mm	Angled Pre-shaped
MC-PP27131	Y (0.021")	2.7 Fr	130 cm	Straight	100mm	Angled Pre-shaped
MC-PP27151	Y (0.021")	2.7 Fr	150 cm	Straight	100mm	Angled Pre-shaped
MC-PE27111	Y (0.021")	2.7 Fr	110 cm	Straight	100mm	Angled Shapeable
MC-PE27115	Y (0.021")	2.7 Fr	110 cm	Straight	50mm	Angled Shapeable
MC-PE27131	Y (0.021")	2.7 Fr	130 cm	Straight	100mm	Angled Shapeable
MC-PE27151	Y (0.021")	2.7 Fr	150 cm	Straight	100mm	Angled Shapeable
MC-PP28131	Y (0.021")	2.8 Fr	130 cm	Straight	100mm	Angled Pre-shaped
MC-PP28151	Y (0.021")	2.8 Fr	150 cm	Straight	100mm	Angled Pre-shaped
MC-PP28151ZV	Y (0.021")	2.8 Fr	150 cm	Straight	100mm	Angled Pre-shaped

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MC-PE28111	Y (0.021")	2.8 Fr	110 cm	Straight	100mm	Angled Shapeable
MC-PE28131	Y (0.021")	2.8 Fr	130 cm	Straight	100mm	Angled Shapeable
MC-PE28131ZB	Y (0.021")	2.8 Fr	130 cm	Straight	100mm	Angled Shapeable
MC-PE28151	Y (0.021")	2.8 Fr	150 cm	Straight	100mm	Angled Shapeable
MC-PE28151ZV	Y (0.021")	2.8 Fr	150 cm	Straight	100mm	Angled Shapeable

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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
2022-12-02	3294905	Issued
Current	3871611	Amended – addition of the Overkill approach for the determination of the lethal rate of the sterilization process for the sterilizer N. 2, 3 and 4; change of the internal PCd.

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