

DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**

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

being the manufacturer of:

Progreat

Angiographic Catheter

Product : Angiographic 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 580672) 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, March 12, 2019

(place and date of issue)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION



Appendix A - List of Code Number Structure

<Step-by-step flexibility type>

M C — □ □ □ □ □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	What the character(s) represents	Denotation												
1 - 2	Product	MC: Micro Catheter												
3	Destination	— : For domestic use / export (except U.S.A.)												
4	Trade name	P: Progreat												
5	Specification		Guide wire type				Tip shape of guide wire			Tip shape of catheter/ Radiopaque marker specification				
		A	Without guide wire				Without guide wire			Angled/without marker***				
		B	Without guide wire				Without guide wire			Straight /Single marker				
		C	Without guide wire				Without guide wire			Straight/ without marker**				
		E	Reshapeable				Angled			Straight/without marker				
		P	Pre-shaped				Angled			Straight/without marker				
		Q	Pre-shaped				Double angled			Straight/without marker				
		U	Without guide wire				Without guide wire			Straight/Double marker (Type A)				
		V	Without guide wire				Without guide wire			Straight/Double marker (Type B)				
X	Without guide wire				Without guide wire			90°-angled/ without marker						
6 - 7	Catheter O.D. at distal end	20			24			27			28			
		2.0Fr.			2.4Fr.			2.7Fr.			2.8Fr.			
8 - 9	Usable length of catheter	10	0C	11	1C	12	2C	13	3C	14	4C	15		
		100cm	105cm	110cm	115cm	120cm	125cm	130cm	135cm	140cm	145cm	150cm		
10	Protruding length of guide wire*	A	0	B	2	C	3	D	4	E	5	F	6	
		5mm	10mm	15mm	20mm	25mm	30mm	35mm	40mm	45mm	50mm	55mm	60mm	
		G	7	H	8	J	9	K	1	L	M			
		65mm	70mm	75mm	80mm	85mm	90mm	95mm	100m	110mm	120mm			
									m					
		N	P	Q	R	S	T	U	V	W				
		130m	140m	150m	160m	170mm	180m	190m	200m	250m				
		m	m	m	m		m	m	m	m				
11	Kit contents	(Blank): Standard ♦ With guide wire in the same holder : Catheter mandrel, Lock-type syringe, Inserter, Wire stopper ♦ W/o guide wire : Catheter Mandrel Y : Standard kit + Y-connector												
12	Specification	(Blank if unnecessary)												
	With a marker at the catheter tip (if a guide wire is attached)	B (For standard kit, the eleventh character is "Z".) D (For standard kit, the eleventh character is "Z". In case, guidewire type is double angled.)												
	With a double marker at the catheter tip (if a guide wire is attached)	W (For standard kit, the eleventh character is "Z". In case, guidewire type is double angled.) V (For standard kit, the eleventh character is "Z". In case, guidewire type is angled.)												
	Without a marker at the catheter tip (if a guide wire is attached)	Q (For standard kit, the eleventh character is "Z".)												

*: For product w/o guide wire, the 10th character is skipped (the 11th and 12th characters shift left)



** : For Catheter O.D. at distal end 2.0Fr., without marker type doesn't exist and "C" is used instead of "B"

***:2.0Fr.type is equipped with single marker

<Stepless flexibility type>

M -
 1 2 3 4 5 6 7 8 9 10 11

Character number	Character	Denotation											
1 - 2	Product	MC: (Micro Catheter) Single marker MW: (Micro Catheter) Double marker											
3	Destination	- : For domestic use / export (except U.S.A.)											
4	Simple catheter, Catheter with GW	C: Simple catheter											
5	Specification	A	With angled catheter tip										
		C	Standard										
6	Catheter O.D. at distal end	2											
		2.2Fr.											
7	Usable length of Catheter	A	B	0	C	1	D	2	E	3	F	4	
		85cm	95cm	100cm	105cm	110cm	115cm	120cm	125cm	130cm	135cm	140cm	
		G	5										
		145cm	150cm										
8	*1	Z											
9	*1	Z											
10	*1	Z											
11	Kit contents	Y: Standard kit + Y-connector											

*1: When additional character is required for without-GW product