

## DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**

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

being the manufacturer of:

**Tercross**

**PTA Dilatation Catheter (OTW)**

**Product : PTA Dilatation Catheter (OTW)**

declare that the above products of **Class IIa** 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, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :

TERUMO EUROPE N.V.

Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, February 10, 2020

(place and date of issue)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION

Appendix A - List of Code Number Structure

B D - T □ □ □ □ □ □ □ □  
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters	Denotation
1-2	Product name	BD: PTA CATHETER
3	Destination	-: for export/ domestic use
4	Product name	T: Tercross (OTW)
5-6	Balloon diameter	12: 1.25 mm 15: 1.5 mm 20: 2.0 mm 25: 2.5 mm 30: 3.0 mm 35: 3.5 mm 40: 4.0 mm
7-(8), 9*	Balloon length	20: 20 mm 40: 40 mm 80: 80 mm 120: 120 mm 150: 150 mm 200: 200 mm
(9), 10*	Catheter length	P: 100 cm Q: 148 cm
(10), 11*	Adaptation wire	4: Wire adaptation of 0.014' '
(11), 12*	Place of destination	E: for domestic market/ export

\*:When balloon length is 2 digits, digit numbers are adapted (8)~(11)

When balloon length is 3 digits, digit numbers are adapted 9\*~12\*