

No. DOC-DQ010· 0743B

Rev.10

## **DECLARATION OF CONFORMITY**

## We, TERUMO CORPORATION

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

being the manufacturer of:

## **FINECROSS MG**

**Coronary Micro-Guide Catheter** 

Product: Catheter, Intravascular, Guiding

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 597867) 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

Product code	Effective Shaft Length
NC-F863A	130cm
NC-F865A	150cm