

## **DECLARATION OF CONFORMITY**

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

being the manufacturer of:

### **RADIFOCUS Torque Device**

**Product : Wire Twister**

declare that the above products of **Class I sterile** 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, 5 of the Directive, relating to the "EC Declaration of Conformity" set out in Annex VII, combined with the provisions set out in Annex V "Production Quality Assurance" and by certification of Annex V limited to the aspects of the manufacture concerned with securing and maintaining sterile conditions, under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: DD 60145254 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)

A handwritten signature in blue ink, reading "Toshio Nakashima".

Toshio Nakashima

General Manager

Quality Assurance Department  
TERUMO CORPORATION

## Appendix A - List of Code Number Structure

X X \* R F 0 2 M  
1 2 3 4 5 6 7 8

Character number	Characters	Meaning
1-2	Product type	XX : other (Accessory device)
3	Destination	* : for export
4-5	Product group	RF : RADIFOCUS system
6-7	Accessory device type	02 : Torque Device
8	Package indication	M : Multi-language