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 (GMDN 32881)

declare that the above products of **Class I sterile** are in conformity with the provisions of Annex I and Annex VII of the EC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and have been subject to the following conformity assessment procedure laid down in the 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" limited to the aspects of the manufacture concerned with securing and maintaining sterile conditions, under the supervision of TÜV Rheinland Product Safety GmbH (Registration No.: HD 60012336 0001), as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Researchpark Zone 2 Haasrode, Interleuvenlaan 40,
3001 Leuven, Belgium

Tokyo, November 26, 2007
(place and date of issue)

A. Oguma

Akira Oguma
Director, General Manager
Quality Assurance Department
TERUMO CORPORATION

TERUMO