

DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
Researchpark Zone 2 Haasrode, Interleuvenlaan 40,
3001 Leuven, Belgium

being the manufacturer of:

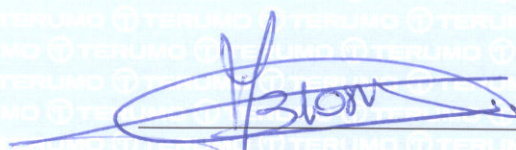
RADIFOCUS® INTRODUCER II (Transradial Kit)

Product: Catheter Introducer

declare that the above product of Class IIa is in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and has 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 System" set out in Annex II, and by certification of Annex II.3, under the supervision of TÜV Rheinland Product Safety (Registration No: HD 60013324 0001), as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Leuven, 28 February 2008

(place and date of issue)



Michel Brasseur, PhD

Manager Quality Systems

and Regulatory Affairs

TERUMO EUROPE N.V.

