

# **DECLARATION OF CONFORMITY**

**We, TERUMO CORPORATION**

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

being the manufacturer of :

## **RADIFOCUS Introducer II**

**Product : Catheter Introducer (GMDN 10678)**

declare that the above products of **Class IIa** are in conformity with the provisions of Annex I and Annex II 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 EC Council Directive 93/42/EEC Article 11, 3(a) relating to the "Full quality assurance" set out in Annex II, under the supervision of TÜV Rheinland (Registration No.: HD 60012340 0001), as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :

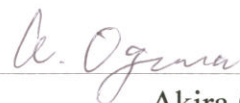
**TERUMO EUROPE N.V.**

**Researchpark Zone 2 Haasrode, Interleuvenlaan 40**

**3001 Leuven, Belgium**

Tokyo, December 12, 2005

(place and date of issue)



**Akira Oguma**

**Director, General Manager  
Quality Assurance Department  
TERUMO CORPORATION**

