Rev.04

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS Haemostasis Valve II

Product : Catheter Introducer

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, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60026344 0001), 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, March 21, 2010
(place and date of issue)

H. Nakagomi

Hiroshi Nakagomi
General Manager
Quality Assurance Department
TERUMO CORPORATION

TERUMO®

Appendix A - List of Code Number Structure

R	F	*	V	A	□	□	□	□
1	2	3	4	5	6	7	8	9

Character number	Denotation
1-2	Product group RF: Radifocus
3	Destination *: for export
4-5	Product type VA: Valve
6	Compatible catheter size (max) Indication : 7 Fr. Size : 7
7	Side tube 1: with side tube
8	Side tube end 3: with three-way stopcock
9	Reserve number M: for Europe Blank: for Japan

Languages for labeling: English, German, French, Italian, Spanish, Dutch, Swedish and Japanese