

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION

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

being the manufacturer of :

RADIFOCUS Optitorque **Angiographic Catheter**

Product : Angiographic Catheter (GMDN 10688)

declare that the above products of **Class III** 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, 1(a) relating to the "Full quality assurance" set out in Annex II, under the supervision of TÜV Rheinland (Registration No.: HD 60012340 0001 ID 60016784 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

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(place and date of issue)



Akira Oguma

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TERUMO CORPORATION

