Rev.07

DECLARATION OF CONFORMITY

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

being the manufacturer of:

TERUMO Dental Needle

Product : Dental Needle

declare that the above products of **Class IIa** are in conformity with the provisions 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, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60077473 0001), Tillystraße 2, 90431 Nürnberg Germany, 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, July 4, 2013
(place and date of issue)

Hiroshi Nakagomi
General Manager
Quality Assurance Department
TERUMO CORPORATION

TERUMO®

Appendix A - List of Code Number Structure

No.	Code	Specification
1,2	DN	Dental needle
3	*	Export
4,5	25	25 gauge
	27	27 gauge
	30	30 gauge
6,7	Length of cannula	Length of cannula (mm)
8	B	Butt end length 13.2mm、EOG sterilization
	F	Butt end length 10.7mm、EOG sterilization
	G	Butt end length 13.2mm、EOG sterilization
	K	Butt end length 10.7mm、Gamma rays sterilization