TERUMO

No.DOC-PQB-TF-MSL
Rev.07

DECLARATION OF CONFORMITY

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

being the manufacturer of:

FINETOUCH Lancet

Product : Lancet tip

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 60121893 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, August 30, 2017
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

MS * □ □ □ □ □ □ □

1 2 3 4 5

1: Product group MS : MEDISAFE
2: Distinction for market *: for export
3: Product GN: Lancet, Lancing device
4: Product name /Quantity in a packaging box
4525: FINETOUCH Lancet 25pieces
4530: FINETOUCH Lancet 30pieces

5: Intended market blank: For Asia
B: For China
C: For Western Europe, Germany
D: For North Europe, UK
F: For Taiwan
G: For Italy