TERUMO

No.DOC-KE-PS1MSL

Rev.09

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 60145252 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, May 28, 2020
(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 C : For Western Europe, Germany D : For North Europe, U.K. G : For Italy