

DECLARATION OF CONFORMITY

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

being the manufacturer of:

TERUMO Syringe

Product: Hypodermic Syringe

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

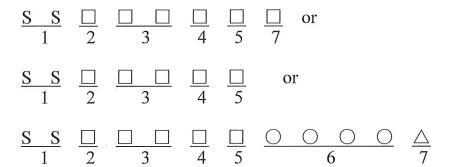
Tokyo, February 10, 2020 (place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

No.DOC- KE-PS1SS

Rev.11

Appendix A - List of Code Number Structure



- 1. Product group (product type) (one digit)
 - SS: Syringe
- 2. Destination (Japan and overseas) (two digits)
 - : Japan ★ : Overseas
- 3. Nominal capacity (product type) (two digits)
 - 02:2.5mL
 - 05:5mL
 - 10:10mL
 - 20:20mL
 - 30:30mL
 - 50:50mL
- 4. Cylinder head shape (one or two digits)
 - S: Luer Slip tip
 - L: Luer Lock tip
 - ES: Eccentric Luer Slip tip
 - C: Catheter tip
- 5. Others
 - E: Electron beam sterilization
- 6. Injection needle type (four digits)
 - Upper two digits: Needle gauge
 - Lower two digits: Needle length
- 7. Last digit
 - 1: CE mark is indicated.