

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

Appendix A - List of Code Number Structure

$$\frac{S}{1} \frac{S}{2} \frac{\square}{3} \frac{\square}{4} \frac{\square}{5} \frac{\square}{7} \text{ or}$$

$$\frac{S}{1} \frac{S}{2} \frac{\square}{3} \frac{\square}{4} \frac{\square}{5} \text{ or}$$

$$\frac{S}{1} \frac{S}{2} \frac{\square}{3} \frac{\square}{4} \frac{\square}{5} \frac{\bigcirc}{6} \frac{\bigcirc}{7} \frac{\bigcirc}{7} \frac{\bigcirc}{7} \frac{\triangle}{7}$$

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.