

### **TERUMO CORPORATION**

44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan Telephone: +81-3-3374-8111 / Facsimile: +81-3-3374-8399

Kofu Factory

1727-1, Tsuiji Arai, Showa-cho, NAKAKOMA-GUN, YAMANASHI, 409-3853, Japan

Telephone: +81-55-275-7111 / Facsimile: +81-55-275-7186

Date: 26 February 2024

To whom it may concern

### **STATEMENT**

We, TERUMO CORPORATION (Japan), 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, being the legal manufacturer of the **TERUMO SYRINGE**, hereby declare that these products bear the CE mark confirming compliance with the essential requirements of the Medical Device Regulation (EU) 2017/745, and are in compliance with the Commission Regulation 722/2012 (repealing Commission Directive 2003/32/EC) laying down particular requirements in relation to the placing on the market and/or putting into service of medical devices manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

To the best of our knowledge and based on information received from our suppliers, we confirm that in case substances (tallow based oleo chemicals) of animal origin are present, being the case for the used polypropylene, they have been subject to treatment (re-esterification or hydrolyse at minimum 250°C under 50 atm for 3 hours continuously) in order to inactivate BSE/TSE risks and are consequently compliant with the notification from Japanese Ministry of Health, Labour and welfare.

K. Hanagata

Kunihiko Hanagata General manager Quality Assurance Department Kofu Factory, TERUMO CORPORATION



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Date: 4 March 2024

To whom it may concern

# **STATEMENT**

We, Terumo Corporation (Japan), 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, being the legal manufacturer of the TERUMO SYRINGE, hereby declare that:

- The above-mentioned product itself and its packaging both do not contain components made of Melamine.

Sincerely yours,

K. Hanagata

Kunihiko Hanagata General manager Quality Assurance Department Kofu Factory, TERUMO CORPORATION



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We; Terumo Corporation (Japan), 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, being the legal manufacturer of the TERUMO SYRINGE, hereby declare that:

- The above-mentioned product itself and its packaging both do not contain components made of Nitrosamine.

Sincerely yours,

Kunihiko Hanagata General manager

K. Hanagata

**Quality Assurance Department** 

Kofu Factory, TERUMO CORPORATION