



EU DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
with Single Registration Number: JP-MF-000017478

being the manufacturer of:

TERUMO SYRINGE

[INFUSION AND IRRIGATION SYRINGES, SINGLE-USE]

Intended purpose:

The TERUMO Syringe is an apparatus used for injecting fixed amount of solution in the endermic, hypodermic, muscle tissues or blood vessels, or other body cavities, or sampling the blood or other body fluids, which can be used instantaneously and intended for use only once.

Basic UDI-DI: 498735037SS3X

Related product codes: See Appendix A (full list of active codes)

declare that the above product of **Class IIa** is in conformity with the applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 52.6 of the Regulation, relating to the “Conformity assessment based on a quality management system and on assessment of technical documentation” set out in Annex IX, and by certification of Annex IX Chapter I & III (EU quality management system certificate number HZ 1485480-1), under the supervision of TÜV Rheinland LGA Products GmbH as Notified Body authorized by the GERMAN Competent Authority and carrying the Notified Body No. 0197.

There is no reference to Common Specifications that have been used to within the conformity assessment for Regulation (EU) 2017/745.

Authorised Representative: TERUMO EUROPE N.V.
Authorised Address: Interleuvenlaan 40, 3001 Leuven, BELGIUM
with Single Registration Number: BE-AR-000001433

This EU declaration of conformity is issued under our sole responsibility.



Rev. 05
DoC No. DOC- KE-PS4SS
Reference to. KE-PS4SS

Tokyo , 2024-03-01

(place and date of issue)

DocuSigned by:

A handwritten signature in blue ink that reads "Toshio Nakashima".



Signer Name: Toshio Nakashima

Signing Reason: I approve this document

Signing Time: 2024-03-01 | 9:36:39 午前 JST

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Toshio Nakashima

General Manager

Quality Assurance Department

For and on behalf of

TERUMO CORPORATION

**Appendix A – Related product codes**

Product Code	UDI-DI Code
SS*02LE1	04987350702562
SS*02SE1	04987350708984
SS*02SE21161	04987350709004
SS*02SE21251	04987350709028
SS*02SE21381	04987350709042
SS*02SE22381	04987350709066
SS*02SE23251	04987350709080
SS*02SE23321	04987350709103
SS*02SE25161	04987350709127
SS*05LE1	04987350702609
SS*05SE1	04987350706324
SS*10LE1	04987350702647
SS*20ESE1	04987350700742
SS*30LE1	04987350701985
SS*30ESE1	04987350700766