EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60145254 0001

Report No.: 12031336 022

Manufacturer:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo
151-0072 Japan

Products: see attachement for products included

Replaces Approval, Registration No.: DD 60121892 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-12-23

Date: 2019-12-23

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Grabazei Alexandru
Date: 2021.12.20 20:07:15 EET
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Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60145254 0001
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For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Sampling Site Coupler
- Radial Artery Hemostasis Band
- Wire Twister

For the following medical devices the scope covers only the aspects of manufacture concerned with the conformity of the products with the metrological requirements:

- Blood Collection Scale

TÜV Rheinland LGA Products GmbH TÜVRheinland® III Zertifizierungsstelle

Notified Body

Date: 2019-12-23

M.Sc. M. Aihara