

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60145252 0001

**Report No.:** 12031336 018

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

**Products:** see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2019-12-23

**Date:** 2019-12-23



Notified Body

*M. Aihara*  
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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**


**Registration No.:** HD 60145252 0001  
**Report No.:** 12031336 023

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

**Products included:**

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

**Notified Body**

  
**M.Sc. M. Aihara**



**Date: 2020-10-23**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60145252 0001  
**Report No.:** 12031336 023

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

**Products included:**

- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer
- Portable insulin infusion pump
- Portable insulin infusion administration set

**Notified Body**



**Date:** 2020-10-23

*M. Aihara*  
**M.Sc. M. Aihara**