

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

**Registration No.:** DD 60147309 0001

**Report No.:** 12031274 008

**Manufacturer:** Terumo (Philippines) Corporation  
124 East Main Avenue  
Laguna Technopark, Binan,  
Laguna, 4024  
Philippines

**Products:** See attachments for products and sites included  
Replaces Approval, Registration No.: DD 60108472 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:** 2020-05-01

**Date:** 2020-05-01



**Notified Body**

  
Takashi Matsuda

**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.:** DD 60147309 0001  
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124 East Main Avenue  
Laguna Technopark, Binan,  
Laguna, 4024  
Philippines

Manufacturing site included:

Terumo (Philippines) Corporation  
128 East Main Avenue, Laguna Technopark, Binan, Laguna,  
4024, Philippines

Aspects of manufacturing concerned with securing and  
maintaining sterile conditions:

- Urinary Drainage Bags

Sterilization (Electron Beam Irradiation) site included:

Terumo (Philippines) Corporation  
124 East Main Avenue, Laguna Technopark, Binan, Laguna,  
4024, Philippines

**Date:** 2020-05-01



**Notified Body**

*T. Matsuda*

**Takashi Matsuda**

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

**Attachment to  
Certificate**

**Registration No.:** DD 60147309 0001  
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124 East Main Avenue  
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Laguna, 4024  
Philippines

Products included:

- Syringes with Needles
- Intravenous Catheters
- Safety Needles
- Syringes with Safety Needles
- Syringes without Needles
- Hypodermic Needles

Aspects of manufacturing concerned with securing and maintaining sterile conditions:

- Urinary Drainage Bags
- Syringes for Oral / Enteral

**Date:** 2020-05-01



**Notified Body**

*T. Matsuda*

**Takashi Matsuda**