

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
Report No.: 12031274 008

Manufacturer: Terumo (Philippines) Corporation
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
Report No.: 12031274 008

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