



TÜVRheinland®

EC Certificate

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

Registration No.: HD 60075259 0001

Report No.: 31193020 001

Manufacturer: Terumo Medical Corporation
950 Elkton Boulevard
Elkton MD 21921
USA

Products: Insulin Syringes, Follicle Stimulating Hormone Syringe,
IV Catheters, Hypodermic Needles, Introducer Kit,
Guiding Sheath, Injection Plug, Allergy Syringes, and
Support Catheter

Replaces Approval, Registration No.: HD 60017109 0001

Expiry Date: 2017-02-16

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: 2012-02-27

Date: 2012-02-27



Notified Body

B. Ludovico

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.