By Royal Charter

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** **CE 554734**

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

In respect of:

**The Design and Manufacture of Balloon Dilatation Catheters, PTCA Guidewires, Angiographic Catheters, MicroGuide catheters, Coronary Imaging Catheters and coronary optical coherence tomography system.**

**Those aspects of Annex II related to securing and maintaining the sterility of the MDU cover, Extension Wires, and related accessories.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **30 October 2009** Date: **01 August 2014** Expiry Date: **12 August 2019**

Digitally signed by Grabazei Alexandru
Date: 2019.02.14 08:12:22 EET
Reason: MoldSign Signature
Location: Moldova

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# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

# List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

| | |
|---|---|
| Certificate No: | **CE 554734** |
| Date: | **01 August 2014** |
| Issued To: | **Terumo Corporation**<br>**44-1, 2-chome**<br>**Hatagaya**<br>**Shibuya-ku**<br>**Tokyo**<br>**151-0072**<br>**Japan** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Terumo Corporation<br>Ashitaka Plant<br>150, Maimaigi-cho, Fujinomiya City,<br>Shizuoka Prefecture 418-0015<br>Japan | **ETO Sterilization**<br>**Manufacture** |
| Terumo Europe N.V.<br>Interleuvenlaan 40<br>3001 Leuven<br>Belgium | **EU Representative** |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 554734**

Date: **01 August 2014**

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**44-1, 2-chome**
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| Date | Reference Number | Action |
|---|---|---|
| 30 October 2009 | 7443727 | First Issue – Transfer from another Notified Body |
| 17 September 2010 | 7560390 | Certificate renewal |
| 23 December 2011 | 7778290 | Addition of "Angiographic Catheters" to the scope of the certificate. Additional service supplied for ETO sterilization at the Terumo Ashitaka Plant. |
| 30 March 2012 | 7730762 | Update to scope of certificate to add Coronary Imaging Catheters. |
| 21 December 2012 | 7916383 | Extension to scope to include LUNAWAVE. |
| 18 April 2013 | 7948395<br>7959985 | Optical Coherence Tomography System (LUNAWAVE) was introduced under 7916383 in Dec 2012. Brand name 'LUNAWAVE' has now been removed from scope. This does not affect the device types covered by the certificate.<br>Extension of scope to include Class I sterile MDU cover and accessories. |
| 4 June 2013 | 7974363 | Extension to scope to include micro-guide catheters. |
| 4 June 2014 | 8164373 | Certificate renewal. |
| 1 August 2014 | 8196034 | Addition of "PTCA Guidewires" and "sterility of…Extension Wires" to the scope. |