

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-10-30**

Date: **2019-08-12**

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

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 554734

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Number	Device Name	Intended purpose per IFU
Class III		
---	RyujinPlus	See CE 554735
---	Tazuna	See CE 554735
---	Hiryu	See CE 599214
---	RyujinPlus OTW	See CE 578316
---	Accuforce	See CE 608484
---	Ryurei	See CE 661655
---	Progreat	See CE 580672
---	Finecross MG	See CE 597867
---	Runthrough NS	See CE 613749
---	FastView	See CE 585621

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1202	LUNAWAVE	---
Class Is		
MD 0106	RunthroughNS Extension wire	---
MD 0106	Fast View MDU cover	---

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List of Significant Subcontractors

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

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Subcontractor:**Service(s) supplied**

SUZUKI Co., Ltd.
2150-1 Ogawara
Suzaka-shi
Nagano
382-8588
Japan

Manufacture

Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho, Fujinomiya City,
Shizuoka Prefecture 418-0015
Japan

Design
Development
ETO Sterilization
Manufacture

Terumo Europe N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

EU Representative

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Tokyo
151-0072
Japan

Subcontractor:

Service(s) supplied

Ueda Japan Radio Co., Ltd.
 2805-72
 Nagase
 Ueda-shi
 Nagano
 386-0407
 Japan

Manufacture

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Certificate History

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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 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. 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.

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Date	Reference Number	Action
27 April 2018	8942575	Added design and development service to Terumo Ashika Plant subcontractor.
04 March 2019	7778938	Traceable to NB 0086.
Current	9789827	Certificate Renewal. Added products table and subcontractors Ueda Japan Radio and SUZUKI.

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