

# EC Certificate - Full Quality Assurance System

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

**No.** **CE 597042**  
**Issued To:** **Blue Medical Devices B.V.**  
**Panovenweg 7**  
**5708 HR Helmond**  
**The Netherlands**

In respect of:

**Design and Manufacture of Sterile PTCA catheters, Drug-eluting Balloon Catheters and stents with associated systems for coronary and peripheral use.**

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **27 July 2016**

Date: **14 March 2017**

Expiry Date: **14 March 2022**

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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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## List of Significant Subcontractors

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

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Meko Laser Material Processing Im Kirchenfelde 12-14 D 31157 Sarstedt/Hannover Germany	<b>Manufacture</b>
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 B-4800 Verviers Belgium	<b>ETO Sterilization</b>
Synergy Health Ede B.V. Morsestraat 3 6716 AH Ede The Netherlands	<b>Gamma Sterilization</b>

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## Certificate History

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Date	Reference Number	Action
27 July 2016	8453676	First Issue – Transfer from another Notified Body
14 March 2017	8675181	Certificate Renewal. Word sterile added to scope. Address updated for Sterigenics Belgium.

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