



# EC Certificate - Full Quality Assurance System

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

**No.** CE 02248  
**Issued To:** **Nagor Limited**  
**129 Deerdykes View**  
**Westfield Industrial Estate**  
**Cumbernauld**  
**Glasgow**  
**G68 9HN**  
**United Kingdom**

In respect of:

**The design and manufacture of body contouring implants, specifically:  
gel filled implants, saline fill implants, solid elastomer implants,  
tissue expansion devices and associated sizing devices**

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: **01 April 1999**

Date: **26 March 2014**

Expiry Date: **01 April 2019**

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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.



# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 02248**  
Date: **26 March 2014**  
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<b>Date</b>	<b>Reference Number</b>	<b>Action</b>
26 March 2014	8125394	Certificate renewal. Administrative update to certificate format

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# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 02248

Issued To:

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Westfield Industrial Estate  
Cumbernauld  
Glasgow  
G68 9HN  
United Kingdom**

**This certificate is issued under the OWN BRAND LABELLING process**

### OEM Information

<b>Name</b>	Biosil Limited
<b>Address</b>	127 Deerdykes View Westfield Industrial Estate Cumbernauld Glasgow G68 9HN United Kingdom
<b>Notified Body</b>	BSI
<b>Certificate No.</b>	CE 01191
<b>Scope</b>	The design and manufacture of body contouring implants, specifically: gel filled implants, saline fill implants, solid elastomer implants, tissue expansion devices and associated sizing devices
<b>Issue / Reissue Date</b>	14 February 1996 / 20 January 2011
<b>Route to Conformity</b>	Directive 93/42/EEC, Annex II, Section 3.2

First Issued: **01 April 1999**

Date: **26 March 2014**

Expiry Date: **01 April 2019**

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.

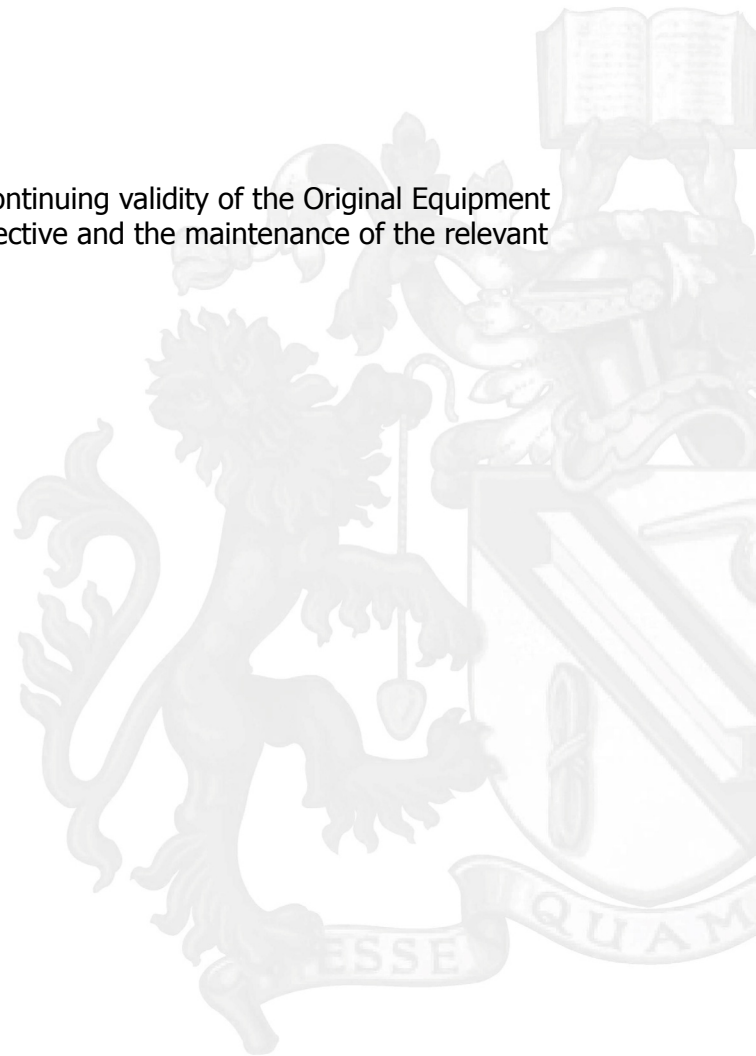
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The validity of this OBL certificate is conditional on the continuing validity of the Original Equipment Manufacturer's certification under the Medical Device Directive and the maintenance of the relevant control exercised by the Own Brand Labeller.



First Issued: **01 April 1999**

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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>
Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton Derbyshire DE55 4NJ United Kingdom	<b>ETO Sterilization</b>
Biosil Limited Ivanhoe Industrial Estate Tournament Way Ashby-de-La-Zouch Leicestershire LE65 2UU United Kingdom	<b>Manufacture</b>

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