

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, 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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1999-04-01**

Date: **2020-06-10**

Expiry Date: **2024-04-01**

...making excellence a habit.™

Page 1 of 2

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

Supplementary Information to CE 02248

Issued To:

Nagor Limited
129 Deerdykes View
Westfield Industrial Estate
Cumbernauld
Glasgow
G68 9HN
United Kingdom

Number	Device Name	Intended purpose per IFU
Class III		
---	Silicone Gel-Filled Mammary Implants	See CE 612851
---	Integrated Valve Tissue Expanders (IVTE)	See CE 633491
---	Sterile Smooth Opaque gel filled mammary implants	See CE 719612
Class IIb		
GMDN 35277	Testicular Implants	To replace organs lost by trauma or surgical intervention.
Class IIa		
SMD0106	Inflatable Mammary Sizers	---
SMD0106	Gel Filled Mammary Sizers	---

First Issued: **1999-04-01**

Date: **2020-06-10**

Expiry Date: **2024-04-01**

...making excellence a habit.™

Page 2 of 2

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.

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.

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 02248**
 Date: **2020-06-10**
 Issued To: **Nagor Limited**
129 Deerdykes View
Westfield Industrial Estate
Cumbernauld
Glasgow
G68 9HN
United Kingdom

Subcontractor:	Service(s) supplied
Biosil Limited 117 Deerdykes View Westfield Industrial Estate Cumbernauld, Glasgow G68 9HN United Kingdom	Dry Heat Sterilization (Thermic sterilization with dry heat)
Biosil Limited 127/129 Deerdykes View Westfield Industrial Estate Cumbernauld, Glasgow G68 9HN United Kingdom	Finished Device Supplier
GC Aesthetics (Management) Limited Suite 601 Q House Furze Road Sandyford Industrial Estate Dublin 18 Ireland	EU Representative

...making excellence a habit.™

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 02248**
Date: **2020-06-10**
Issued To: **Nagor Limited**
129 Deerdykes View
Westfield Industrial Estate
Cumbernauld
Glasgow
G68 9HN
United Kingdom

Subcontractor:

Service(s) supplied

Sterigenics UK Limited
Cotes Park Lane
Somercotes
Alfreton
DE55 4NJ
United Kingdom

ETO Sterilization

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 02248**
 Date: **2020-06-10**
 Issued To: **Nagor Limited**
129 Deerdykes View
Westfield Industrial Estate
Cumbernauld
Glasgow
G68 9HN
United Kingdom

Date	Reference Number	Action
24 March 2014	8125394	Certificate renewal. Administrative update to certificate format.
08 December 2016	8634477	Addition of Biosil Limited, Glasgow, as finished goods supplier.
21 August 2017	8792908	Removal of saline mammary implants.
22 February 2019	7779519	Traceable to NB 0086
03 April 2019	9722778	Certificate renewal. Removal of Ashby Site of Biosil Ltd (Ivanhoe Industrial Estate, Tournament Way, Ashby-de-la-Zouch). Addition of dry heat sterilization site, Biosil Limited 117 Deerdykes view Westfield Industrial Estate Cumbernauld, Glasgow, G68 9HN United Kingdom. Correction of Sterigenics UK limited address from Cotes Park Estate Somercotes Alfreton DE55 4NJ United Kingdom to Cotes Park Lane Somercotes Alfreton DE55 4NJ United Kingdom. Addition of Product Table.
Current	3094832	Addition of GC Aesthetics (Management) Limited Suite 601, Q House, Furze Road, Sandyford Industrial Estate Dublin 18 Ireland as EU Authorized Representative. Extension to scope to include PERLE™ Sterile Smooth Opaque gel filled mammary implants.

...making excellence a habit.™

Page 1 of 1

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.