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**

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Supplementary Information to CE 02248

Issued To:

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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	---

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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**

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List of Significant Subcontractors

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

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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 Ltd Cotes Park Estate Alfreton DE55 4NJ United Kingdom	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 02248**

Date: **2020-06-10**

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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.
10 June 2020	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.

EC Certificate - Full Quality Assurance System Certificate History

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

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
11 February 2022	3615742	Removal of Inflatable Mammary Sizers

Inspiring trust for a more resilient world.

11 February 2022

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 02248	93/42/EEC Annex II excluding Section 4	3615742	Removal of Class IIa Inflatable Mammary Sizers from the supplementary table of the certificate.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl