By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 579482**

Issued To: **Nagor Limited**
129 Deerdykes View
Westfield Industrial Estate
Cumbernauld
Glasgow
G68 9HN
United Kingdom

In respect of:

Design, manufacture and final inspection of sterile, single use tissue expanders

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: **2012-05-14** Date: **2020-05-28** Expiry Date: **2022-05-13**

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Supplementary Information to CE 579482

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Number	Device Name	Intended purpose per IFU
Class IIb		
GMDN 45187	Remote Valve Tissue Expanders	To gradually stretch the tissue adjacent to the implantation area (normally the skin). Once the tissue has expanded sufficiently, the device is removed and the extra tissue can then be used where it is required (burns, scars, etc.). Tissue expansion can also be used in preparation for permanent prosthesis implantation.

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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**
Eurosilicone SAS ZI de la Peyroliére BP 68 Apt 84400 France	**Finished Device Supplier**
GC Aesthetics (Management) Limited Suite 601 Q House Furze Road Sandyford Industrial Estate Dublin 18 Ireland	**EU Representative**
Sterlab 485 avenue de Berlin Allée des Jacarandas Parc d'activités du Plateau de Signes 83870 SIGNES France	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
14 May 2012	7753767	First issue.
06 March 2015	8273241	Update to OEM certificate information.
12 May 2017	8742839	Certificate renewal. Update to certificate template. Addition of subcontractor STERLAB, Vallauris, France for ETO sterilisation and update to subcontractor Eurosilicone SAS, Apt, France to finished device supplier.
22 February 2019	7779519	Traceable to NB 0086
03 June 2019	9750811	Addition of Sterlab site 485 Avenue de Berlin Allee des Jacarandes Parc d'activities du Plateau de Signes 83870 Signes France. Removal of Sterlab site 2027 Chemin Saint Bernard Vallauris 06224 France. Addition of supplementary device table.
Current	3094844	Addition of GC Aesthetics (Management) Limited Suite 601, Q House, Furze Road, Sandyford Industrial Estate Dublin 18 Ireland as EU Authorized Representative.