

EC Certificate - Full Quality Assurance System

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

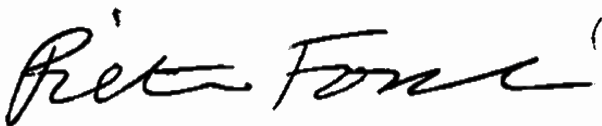
No. CE 579482
Issued To: **Nagor Limited**
129 Deerdykes View
Westfield Industrial Estate
Cumbernauld
Glasgow
G68 9HN
United Kingdom

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 0086):



Pietro Foschi - Strategic Delivery Director

First Issued: **14 May 2012**

Date: **06 March 2015**

Expiry Date: **13 May 2017**

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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 579482**
Date: **06 March 2015**
Issued To: **Nagor Limited
129 Deerdykes View
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Cumbernauld
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Date	Reference Number	Action
14 May 2012	7753767	First issue.
06 March 2015	8273241	Update to OEM certificate information

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Supplementary Information to CE 579482

Issued To:

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129 Deerdykes View
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Glasgow
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United Kingdom

This certificate is issued under the OWN BRAND LABELLING process

OEM Information

Name	EUROSILICONE S.A.S.
Address	Z.1. de la Peyroliere FR-84400 APT
Notified Body	Societe Nationale de Certification et d'Homologation
Certificate No.	0043056-16
Scope	Design, manufacture and final inspection of implants for reconstructive body contouring and aesthetic surgery
Issue / Reissue Date	09-08-2015
Route to Conformity	Directive 93/42/EEC, Annex II, Section 3.2

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: **14 May 2012**

Date: **06 March 2015**

Expiry Date: **13 May 2017**

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