

BSI.



By Royal Charter

EC Certificate - Full Quality Assurance System

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

NOT 7.1.1

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

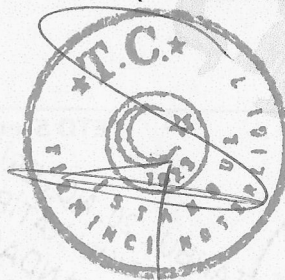
In respect of:

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices



İSTANBUL 20. NOTERİ
İMZA YETKİLİ KATİP
SERHAN MANDACI

First Issued: 1999-04-01

Date: 2017-08-21

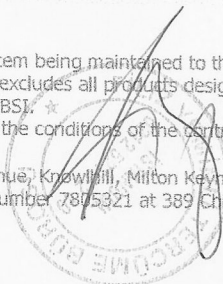
Expiry Date: 2019-04-01

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, Tel: + 44 345 080 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.





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: **2017-08-21**
Issued To: **Nagor Limited
129 Deerdykes View
Westfield Industrial Estate
Cumbernauld
Glasgow
G68 9HN
United Kingdom**

Subcontractor:

Service(s) supplied

Biosil Limited
127 Deerdykes View
Westfield Industrial Estate
Cumbernauld, Glasgow
G68 9HN
United Kingdom

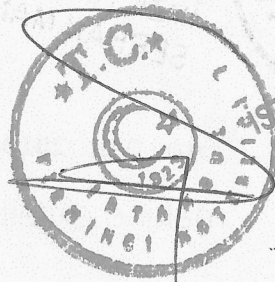
Finished Device Supplier

Biosil Limited
Ivanhoe Industrial Estate
Tournament Way
Ashby-de-La-Zouch
Leicestershire LE65 2UU
United Kingdom

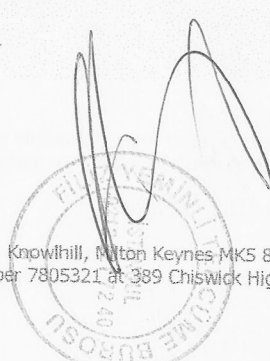
Manufacture

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

ETO Sterilization



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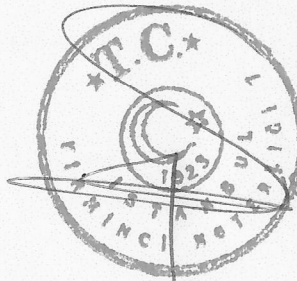


EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 02248**
 Date: **2017-08-21**
 Issued To: **Nagor Limited**
129 Deerdykes View
Westfield Industrial Estate
Cumbernauld
Glasgow
G68 9HN
United Kingdom

017111

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.
Current	8792908	Removal of saline mammary implants.



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