



EC Design-Examination Certificate

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

No.**CE 612851**

Issued To:

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

In respect of:

Silicone Gel-Filled Mammary Implants

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **26 March 2014**Date: **26 March 2014**Expiry Date: **25 March 2019**

...making excellence a habit.™

Page 1 of 7

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 certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 612851

Issued To:

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

GFX gel-filled mammary implant range:

CATALOGUE NUMBERS	DESCRIPTION
GFX 80-800	Gel-filled textured high profile
GFX-LP 120-460	Gel-filled textured low profile
GFX-EHP 135-765	Gel-filled textured extra high profile

RGI gel-filled mammary implant range:

CATALOGUE NUMBERS	DESCRIPTION
RGI-D 120-400	Gel-filled smooth low profile
RGI-DH 140-500	Gel-filled smooth high profile
RGI-DEH 135-765	Gel-filled smooth extra high profile

First Issued: **26 March 2014**

Date: **26 March 2014**

Expiry Date: **25 March 2019**

Page 2 of 7

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 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: + 44 845 080 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 Design-Examination Certificate

Supplementary Information to CE 612851

Issued To:

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

9 cell Cogel anatomical gel-filled mammary implant range:

CATALOGUE NUMBERS	DESCRIPTION
XF1 120 – XF1 430	Soft, form stable cohesive gel filled textured anatomical - Full height, low projection (CoGel).
XF2 145 – XF2 505	Soft, form stable cohesive gel filled textured anatomical - Full height, moderate projection (CoGel).
XF3 170 – XF3 540	Soft, form stable cohesive gel filled textured anatomical - Full height, high projection (CoGel).

CATALOGUE NUMBERS	DESCRIPTION
XM1 105 – XM1 410	Soft, form stable cohesive gel filled textured anatomical - moderate height, low projection (CoGel).
XM2 130 – XM2 445	Soft, form stable cohesive gel filled textured anatomical - moderate height, moderate projection (CoGel).
XM3 155 – XM3 520	Soft, form stable cohesive gel filled textured anatomical - moderate height, high projection (CoGel).

First Issued: **26 March 2014**

Date: **26 March 2014**

Expiry Date: **25 March 2019**

Page 3 of 7

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 certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 612851

Issued To:

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

CATALOGUE NUMBERS	DESCRIPTION
XL1 105 – XL1 380	Soft, form stable cohesive gel filled textured anatomical - Low height, low projection (CoGel).
XL2 120 – XL2 425	Soft, form stable cohesive gel filled textured anatomical - Low height, moderate projection (CoGel).
XL3 160 – XL3 480	Soft, form stable cohesive gel filled textured anatomical - Low height, high projection (CoGel).

Textured Impleo gel-filled mammary implant range:

CATALOGUE NUMBERS	DESCRIPTION
IMP-MR 150 – IMP-MR 460	Soft high Cohesive Gel-filled textured - Moderate range
IMP-HR 150 – IMP-HR 560	Soft High Cohesive Gel-Filled textured – High Range
IMP-EHR 150 – IMP-EHR 620	Soft High Cohesive Gel-Filled textured – Extra High Range

First Issued: **26 March 2014**

Date: **26 March 2014**

Expiry Date: **25 March 2019**

Page 4 of 7

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 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: + 44 845 080 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 Design-Examination Certificate

Supplementary Information to CE 612851

Issued To:

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

Smooth Impleo gel-filled mammary implant range:

CATALOGUE NUMBERS	DESCRIPTION
IMP-SMR 150 – IMP-SMR 460	Soft High Cohesive Gel-Filled Smooth – Moderate Range
IMP-SHR 150 – IMP-SHR 560	Soft High Cohesive Gel-Filled Smooth – High Range
IMP-SEHR 150 – IMP-SEHR 620	Soft High Cohesive Gel-Filled Smooth – Extra High Range

First Issued: **26 March 2014**

Date: **26 March 2014**

Expiry Date: **25 March 2019**

Page 5 of 7

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 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: + 44 845 080 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 Design-Examination Certificate

Supplementary Information to CE 612851

Issued To:

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

Old CoGel gel-filled mammary implant range:

CATALOGUE NUMBERS	DESCRIPTION
CoGel-XR 100- CoGel-XR 620	High cohesive gel-filled textured round - low profile
CoGel- XRH 125 – CoGel-XRH 795	High cohesive gel-filled textured round - high profile
CoGel-XREH 120 – CoGel-XREH 640	High cohesive gel-filled textured round - extra high profile
CoGel-XL 190 – CoGel-XL 560	High cohesive gel-filled anatomical - low height
CoGel-XM 190 – CoGel-XM 560	High cohesive gel-filled anatomical - moderate height
CoGel-XA 190 – CoGel-XA 630	High cohesive gel-filled anatomical - full height

First Issued: **26 March 2014**

Date: **26 March 2014**

Expiry Date: **25 March 2019**

Page 6 of 7

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 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: + 44 845 080 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 Design-Examination Certificate

Supplementary Information to CE 612851

Issued To:

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

Certificate History

Date	Reference Number	Action
26 March 2014	10145954	First issue. Traceable to CE 02248 dated 26 Feb 2009.



First Issued: **26 March 2014**

Date: **26 March 2014**

Expiry Date: **25 March 2019**

Page 7 of 7

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 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: + 44 845 080 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 Design-Examination Certificate

Supplementary Information to CE 612851

Issued To:

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

**This certificate is issued under the OWN BRAND LABELLING process
The corresponding Annex II, Section 3.2 certificate is CE 02248
OEM Information**

Name	Biosil Ltd
Address	127 Deerdykes View Westfield Industrial Estate Cumbernauld Glasgow G68 9HN United Kingdom
Notified Body	BSI
Certificate No.	CE 82021
Scope	Silicone Gel-Filled Mammary Implants
Issue / Reissue Date	27 February 2004 / 26 February 2014
Route to Conformity	Directive 93/42/EEC, Annex II, Section 4

First Issued: **26 March 2014**

Date: **26 March 2014**

Expiry Date: **25 March 2019**

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 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: + 44 845 080 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.

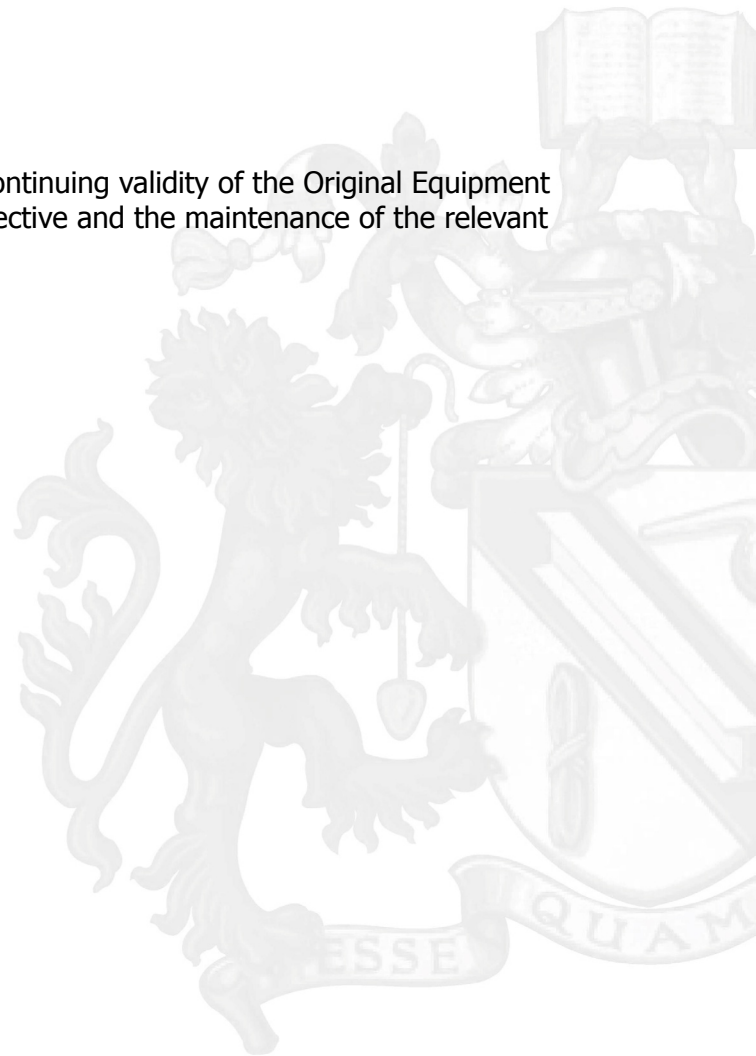
EC Design-Examination Certificate

Supplementary Information to CE 612851

Issued To:

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

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: **26 March 2014**

Date: **26 March 2014**

Expiry Date: **25 March 2019**

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 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: + 44 845 080 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.