



EC Design-Examination Certificate

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

No.**CE 612852**

Issued To:

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

In respect of:

Saline-Fill 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.™

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

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Product

Saline-Fill Mammary Implants

Catalogue No.	Description
SFX-LP	Saline Fill Textured Low Profile
SFX-HP	Saline Fill Textured High Profile
SFS-LP	Saline Fill Smooth Low Profile
SFS-HP	Saline Fill Smooth High Profile

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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.

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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**

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**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 81356
Scope	Saline-Fill 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**

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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.



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