

# DECLARATION OF CONFORMITY

## Class III

### SILICONE GEL-FILLED MAMMARY IMPLANTS

WE, NAGOR LTD, DECLARE THAT THE PRODUCTS DESCRIBED WITHIN THIS DOCUMENT CONFORM TO THE REQUIREMENTS OF

**COMMISSION DIRECTIVE 2003/12/EC OF 3 FEBRUARY 2003 ON THE RECLASSIFICATION OF BREAST IMPLANTS IN THE FRAMEWORK OF DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC CONCERNING MEDICAL DEVICES**

**IN ACCORDANCE WITH ARTICLE 11 PARAGRAPH 1 (a), THIS CLASS III DEVICE SHALL FOLLOW THE PROCEDURE RELATING TO THE EC DECLARATION OF CONFORMITY SET OUT IN ANNEX II (FULL QUALITY ASSURANCE) OF THE COUNCIL DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC CONCERNING MEDICAL DEVICES**

AS TRANSPOSED INTO NATIONAL LAW BY THE UK MEDICAL DEVICE REGULATIONS 1994

Full Quality Assurance Certificate No. CE 02248  
Design Examination Certificate No. CE 612851

Notified Body:

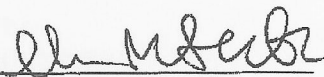
BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom (Notified Body Number 0086)

#### GEL-FILLED MAMMARY IMPLANT PRODUCT RANGE CODES

GFX 80 - GFX 800	XL3 160 - XL3 480
GFX-LP 120 - GFX-LP 460	IMP-MR 150 - IMP-MR 460
GFX-EHP 135 - GFX-EHP 765	IMP-HR 150 - IMP-HR 560
RGI-D 120 - RGI-D 400	IMP-EHR 150 - IMP-EHR 620
RGI-DH 140 - RGI-DH 500	CoGel-XR 100- CoGel-XR 620
RGI-DEH 135 - RGI-DEH 765	CoGel- XRH 125 - CoGel-XRH 795
XF1 120 - XF1 430	CoGel-XREH 120 - CoGel-XREH 640
XM1 105 - XM1 410	CoGel-XL 190 - CoGel-XL 560
XL1 105 - XL1 380	CoGel-XM 190 - CoGel-XM 560
XF2 145 - XF2 505	CoGel-XA 190 - CoGel-XA 630
XM2 130 - XM2 445	IMP-SMR 150 - IMP-SMR 460
XL2 120 - XL2 425	IMP-SHR 150 - IMP-SHR 560
XF3 170 - XF3 540	IMP-SEHR 150 - IMP-SEHR 620
XM3 155 - XM3 520	

Manufactured by:

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

Signed:   
Chris Brotherston  
Director of RA

Dated: 21 August 2017

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