

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-03-26**

Date: **2020-05-28**

Expiry Date: **2024-03-25**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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Supplementary Information to CE 612851

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
GFX 80	GFX gel-filled mammary implants: gel-filled textured high profile	80	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
GFX 100		100		
GFX 120		120		
GFX 140		140	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
GFX 160		160		
GFX 180		180	Combined breast and chest wall abnormalities.	
GFX 200		200		
GFX 220		220	Replacement of implants for medical reasons.	
GFX 240		240		
GFX 260		260		
GFX 280		280		
GFX 300		300		
GFX 320		320		
GFX 340		340		
GFX 370		370		
GFX 410		410		

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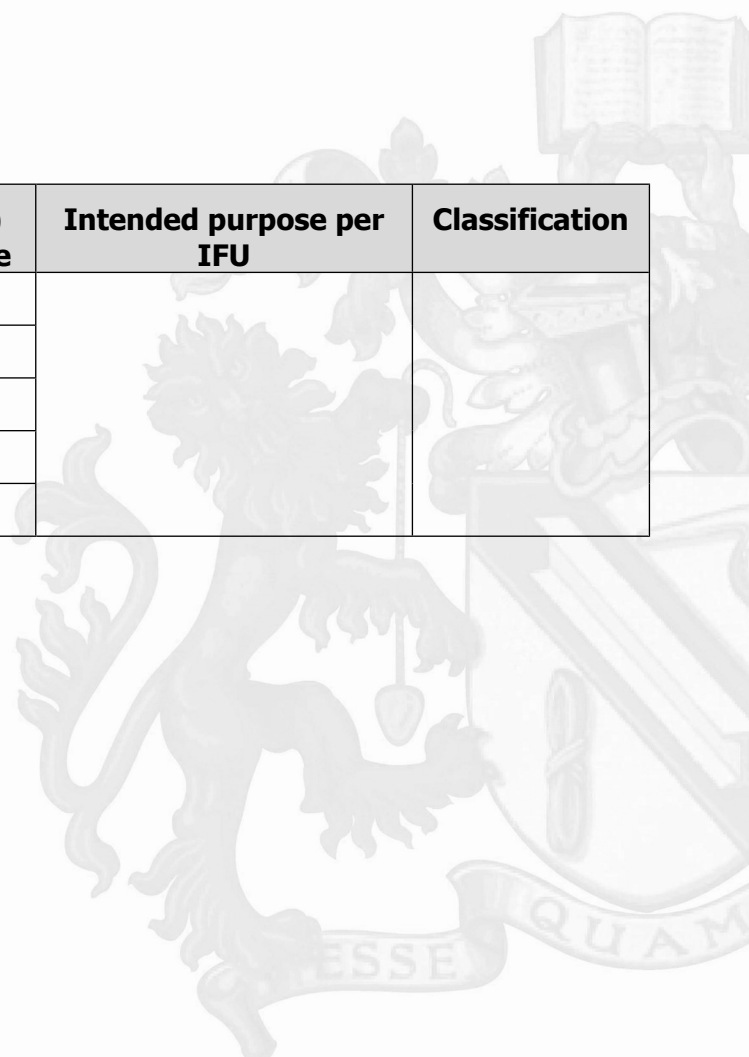
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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
GFX 460		460		
GFX 500		500		
GFX 600		600		
GFX 700		700		
GFX 800		800		



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GFX-LP 120	GFX gel-filled mammary implants: gel-filled textured low profile	120	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
GFX-LP 140		140		
GFX-LP 160		160		
GFX-LP 180		180	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
GFX-LP 200		200		
GFX-LP 220		220	Combined breast and chest wall abnormalities.	
GFX-LP 240		240		
GFX-LP 270		270		
GFX-LP 290		290	Replacement of implants for medical reasons.	
GFX-LP 310		310		
GFX-LP 340		340		
GFX-LP 380		380		
GFX-LP 420		420		
GFX-LP 460		460		

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GFX-EHP 135	GFX gel-filled mammary implants: gel-filled textured extra high profile	135	Reconstruction and augmentation of congenital anomalies of the breast. Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma. Combined breast and chest wall abnormalities. Replacement of implants for medical reasons.	Class III implant
GFX-EHP 155		155		
GFX-EHP 175		179		
GFX-EHP 195		195		
GFX-EHP 215		215		
GFX-EHP 235		235		
GFX-EHP 255		255		
GFX-EHP 275		275		
GFX-EHP 295		295		
GFX-EHP 325		325		
GFX-EHP 345		345		
GFX-EHP 365		365		
GFX-EHP 395		395		
GFX-EHP 425		425		
GFX-EHP 465		465		
GFX-EHP 505		505		
GFX-EHP 555	555			

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GFX-EHP 605		605		
GFX-EHP 655		655		
GFX-EHP 705		705		
GFX-EHP 765		765		

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RGI-D 120	RGI gel-filled mammary implants: gel-filled smooth low profile	120	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
RGI-D 140		140		
RGI-D 160		160		
RGI-D 180		180	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
RGI-D 200		200		
RGI-D 220		220	Combined breast and chest wall abnormalities.	
RGI-D 240		240		
RGI-D 260		260		
RGI-D 280		280	Replacement of implants for medical reasons.	
RGI-D 300		300		
RGI-D 360		360		
RGI-D 400		400		

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RGI-DH 140	RGI gel-filled mammary implants: gel-filled smooth high profile	140	Reconstruction and augmentation of congenital anomalies of the breast. Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma. Combined breast and chest wall abnormalities. Replacement of implants for medical reasons.	Class III implant
RGI-DH 160		160		
RGI-DH 180		180		
RGI-DH 200		200		
RGI-DH 220		220		
RGI-DH 240		240		
RGI-DH 260		260		
RGI-DH 280		280		
RGI-DH 300		300		
RGI-DH 320		320		
RGI-DH 340		340		
RGI-DH 370		370		
RGI-DH 410		410		
RGI-DH 460		460		
RGI-DH 500		500		

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RGI-DEH 135	RGI gel-filled mammary implants: gel-filled smooth extra high profile	135	Reconstruction and augmentation of congenital anomalies of the breast. Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma. Combined breast and chest wall abnormalities. Replacement of implants for medical reasons.	Class III implant
RGI-DEH 155		155		
RGI-DEH 175		179		
RGI-DEH 195		195		
RGI-DEH 215		215		
RGI-DEH 235		235		
RGI-DEH 255		255		
RGI-DEH 275		275		
RGI-DEH 295		295		
RGI-DEH 325		325		
RGI-DEH 345		345		
RGI-DEH 365		365		
RGI-DEH 395		395		
RGI-DEH 425		425		
RGI-DEH 465		465		

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RGI-DEH 505		505		
RGI-DEH 555		555		
RGI-DEH 605		605		
RGI-DEH 655		655		
RGI-DEH 705		705		
RGI-DEH 765		765		

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
XF1-120	9-cell Cogel anatomical gel-filled mammary implants: Soft, form stable cohesive gel-filled textured anatomical – full height, low projection (CoGel)	120	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
XF1-145		145		
XF1-170		170		
XF1-195		195	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
XF1-235		235		
XF1-275		275		
XF1-300		300		
XF1-350		350		
XF1-390		390	Combined breast and chest wall abnormalities. Replacement of implants for medical reasons.	
XF1-430		430		

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XF2-145	9-cell Cogel anatomical gel-filled mammary implants: Soft, form stable cohesive gel-filled textured anatomical – full height, moderate projection (CoGel)	145	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
XF2-170		170		
XF2-200		200		
XF2-230		230	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
XF2-270		270		
XF2-315		315		
XF2-350		350		
XF2-400		400	Combined breast and chest wall abnormalities.	
XF2-450		450		
XF2-505		505	Replacement of implants for medical reasons.	

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XF3-170	9-cell Cogel anatomical gel-filled mammary implants: Soft, form stable cohesive gel-filled textured anatomical – full height, high projection (CoGel)	170	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
XF3-200		200		
XF3-235		235		
XF3-280		280	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
XF3-320		320		
XF3-365		365		
XF3-405		405		
XF3-465		465	Combined breast and chest wall abnormalities.	
XF3-515		515		
XF3-540		540	Replacement of implants for medical reasons.	

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
XM1-105	9-cell Cogel anatomical gel-filled mammary implants: Soft, form stable cohesive gel-filled textured anatomical – moderate height, low projection (CoGel)	105	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
XM1-135		135		
XM1-155		155		
XM1-185		185	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
XM1-215		215		
XM1-250		250		
XM1-275		275		
XM1-325		325	Combined breast and chest wall abnormalities.	
XM1-360		360		
XM1-410		410	Replacement of implants for medical reasons.	

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
XM2-130	9-cell Cogel anatomical gel-filled mammary implants: Soft, form stable cohesive gel-filled textured anatomical – moderate height, moderate projection (CoGel)	130	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
XM2-165		165		
XM2-185		185		
XM2-215		215	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
XM2-250		250		
XM2-290		290		
XM2-320		320		
XM2-370		370	Combined breast and chest wall abnormalities.	
XM2-415		415		
XM2-445		445	Replacement of implants for medical reasons.	

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XM3-155	9-cell Cogel anatomical gel-filled mammary implants: Soft, form stable cohesive gel-filled textured anatomical – moderate height, high projection (CoGel)	155	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
XM3-190		190		
XM3-215		215		
XM3-260		260	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
XM3-300		300		
XM3-335		335		
XM3-375		375		
XM3-440		440	Combined breast and chest wall abnormalities.	
XM3-485		485		
XM3-520		520	Replacement of implants for medical reasons.	

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XL1-105	9-cell Cogel anatomical gel-filled mammary implants: Soft, form stable cohesive gel-filled textured anatomical – low height, low projection (CoGel)	105	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
XL1-120		120		
XL1-140		140		
XL1-170		170	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
XL1-210		210		
XL1-230		230		
XL1-250		250		
XL1-300		300	Combined breast and chest wall abnormalities.	
XL1-330		330		
XL1-380		380	Replacement of implants for medical reasons.	

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XL2-120	9-cell Cogel anatomical gel-filled mammary implants: Soft, form stable cohesive gel-filled textured anatomical – low height, moderate projection (CoGel)	120	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
XL2-145		145		
XL2-170		170		
XL2-195		195	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
XL2-230		230		
XL2-265		265		
XL2-295		295		
XL2-340		340	Combined breast and chest wall abnormalities.	
XL2-385		385		
XL2-425		425	Replacement of implants for medical reasons.	

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XL3-160	9-cell Cogel anatomical gel-filled mammary implants: Soft, form stable cohesive gel-filled textured anatomical – low height, high projection (CoGel)	160	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
XL3-175		175		
XL3-200		200		
XL3-240		240	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
XL3-275		275		
XL3-305		305		
XL3-350		350	Combined breast and chest wall abnormalities.	
XL3-410		410		
XL3-450		450	Replacement of implants for medical reasons.	
XL3-480		480		

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IMP-MR 150	Textured Impleo gel-filled mammary implants: soft, high cohesive gel-filled textured – moderate range	165	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
IMP-MR 180		190		
IMP-MR 210		220		
IMP-MR 240		255	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
IMP-MR 270		278		
IMP-MR 300		300		
IMP-MR 330		340		
IMP-MR 360		365		
IMP-MR 390		390	Combined breast and chest wall abnormalities.	
IMP-MR 420		430	Replacement of implants for medical reasons.	
IMP-MR 460		480		

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IMP-HR 150	Textured Impleo gel-filled mammary implants: soft, high cohesive gel-filled textured – high range	150	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
IMP-HR 180		180		
IMP-HR 210		210		
IMP-HR 240		240	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
IMP-HR 270		270		
IMP-HR 300		300	Combined breast and chest wall abnormalities.	
IMP-HR 330		330		
IMP-HR 360		360	Replacement of implants for medical reasons.	
IMP-HR 390		375		
IMP-HR 420		425		
IMP-HR 460		460		
IMP-HR 520		505		
IMP-HR 560		550		

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IMP-EHR 150	Textured Impleo gel-filled mammary implants: soft, high cohesive gel-filled textured –extra high range	161	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
IMP-EHR 180		180		
IMP-EHR 210		210		
IMP-EHR 240		235	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
IMP-EHR 270		260		
IMP-EHR 300		291	Combined breast and chest wall abnormalities.	
IMP-EHR 330		332		
IMP-EHR 360		360	Replacement of implants for medical reasons.	
IMP-EHR 390		400		
IMP-EHR 420		435		
IMP-EHR 460		460		
IMP-EHR 520		520		
IMP-EHR 560		575		
IMP-EHR 620		620		

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IMP-SMR 150	Smooth Impleo gel-filled mammary implants: soft, high cohesive gel-filled smooth – moderate range	165	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
IMP-SMR 180		190		
IMP-SMR 210		220		
IMP-SMR 240		255	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
IMP-SMR 270		278		
IMP-SMR 300		300		
IMP-SMR 330		340		
IMP-SMR 360		365		
IMP-SMR 390		390	Combined breast and chest wall abnormalities.	
IMP-SMR 420		430	Replacement of implants for medical reasons.	
IMP-SMR 460		480		

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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

Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
IMP-SHR 150	Smooth Impleo gel-filled mammary implants: soft, high cohesive gel-filled smooth – high range	150	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
IMP-SHR 180		180		
IMP-SHR 210		210		
IMP-SHR 240		240	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
IMP-SHR 270		270		
IMP-SHR 300		300	Combined breast and chest wall abnormalities.	
IMP-SHR 330		330		
IMP-SHR 360		360	Replacement of implants for medical reasons.	
IMP-SHR 390		375		
IMP-SHR 420		425		
IMP-SHR 460		460		
IMP-SHR 520		505		
IMP-SHR 560		550		

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
IMP-SEHR 150	Smooth Impleo gel-filled mammary implants: soft, high cohesive gel-filled smooth – extra high range	161	Reconstruction and augmentation of congenital anomalies of the breast.	Class III implant
IMP-SEHR 180		180		
IMP-SEHR 210		210		
IMP-SEHR 240		235	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
IMP-SEHR 270		260		
IMP-SEHR 300		291	Combined breast and chest wall abnormalities.	
IMP-SEHR 330		332		
IMP-SEHR 360		360	Replacement of implants for medical reasons.	
IMP-SEHR 390		400		
IMP-SEHR 420		435		
IMP-SEHR 460		460		
IMP-SEHR 520		520		
IMP-SEHR 560		575		
IMP-SEHR 620		620		

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Certificate History

Date	Reference Number	Action
26 March 2014	10145954	First issue. Traceable to CE 02248 dated 26 Feb 2009.
24 January 2017	10166364	Review of manufacturing solvent change. Certificate template update to reflect new format.
21 August 2017	8790772	Addition of medium outer blister raw material suppliers and widening of the thickness range for the medium outer blisters.
18 February 2019	9645243	Certificate renewal.
22 February 2019	7779519	Traceable to NB 0086
Current	3054952	Reviewed IFU, labels and DoC for addition of EU authorized representative.

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