



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

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

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Supplementary Information to CE 612851

Issued To:

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	/					
Classification	Intended purpose per IFU	Weight (g) Model, Type	Device Name	Catalogue Number		
0000	1011	80		GFX 80		
	Jan 19 19 19 19 19 19 19 19 19 19 19 19 19	100		GFX 100		
		120		GFX 120		
	Reconstruction and	140		GFX 140		
	augmentation of congenital anomalies of	160		GFX 160		
	the breast.	180		GFX 180		
	Reconstruction of the breast following	200		GFX 200		
Class III	subcutaneous mastectomy	220	GFX gel-filled mammary implants:	GFX 220		
implant	and other suitable	240	gel-filled textured	GFX 240		
	mastectomy procedures or trauma.	260	high profile	GFX 260		
	Combined breast and	280		GFX 280		
	chest wall abnormalities.	300		GFX 300		
	Replacement of implants for medical reasons.	320		GFX 320		
	TOT THEUICAL TEASORS.	340		GFX 340		
		370		GFX 370		
		410		GFX 410		

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
GFX 460		460	101	1
GFX 500		500	THE STATE OF	
GFX 600		600		199
GFX 700		700		
GFX 800		800	SA YOUR	

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
GFX-LP 120		120	151	
GFX-LP 140		140		
GFX-LP 160		160	Reconstruction and augmentation of	100
GFX-LP 180	_	180	congenital anomalies of	Chick Or
GFX-LP 200		200	the breast.	
GFX-LP 220	CEN and Ciled	220	Reconstruction of the breast following	A of A
GFX-LP 240	GFX gel-filled mammary implants:	240	subcutaneous mastectomy	Class III
GFX-LP 270	gel-filled textured	270	and other suitable mastectomy procedures or	implant
GFX-LP 290	low profile	290	trauma.	
GFX-LP 310		310	Combined breast and	
GFX-LP 340		340	chest wall abnormalities.	- 10
GFX-LP 380		380	Replacement of implants for medical reasons.	
GFX-LP 420		420	. S. Medical reasons	FORU
GFX-LP 460		460	Carrie D.	14.39

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
GFX-EHP 135		135		
GFX-EHP 155		155	A STATE OF THE STA	
GFX-EHP 175		179	48 May An	Co.
GFX-EHP 195		195	Reconstruction and	(1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
GFX-EHP 215		215	augmentation of	
GFX-EHP 235		235	congenital anomalies of the breast.	
GFX-EHP 255		255	Reconstruction of the	
GFX-EHP 275	GFX gel-filled	275	breast following	
GFX-EHP 295	mammary implants:	295	subcutaneous mastectomy and other suitable	Class III
GFX-EHP 325	gel-filled textured extra high profile	325	mastectomy procedures or	implant
GFX-EHP 345	gradient in gradient	345	trauma.	5 (1)
GFX-EHP 365		365	Combined breast and chest wall abnormalities.	
GFX-EHP 395		395	Replacement of implants	RQII
GFX-EHP 425		425	for medical reasons.	E
GFX-EHP 465		465		
GFX-EHP 505		505		
GFX-EHP 555 First Issued: 2014-		555 e: 2020-05-28	Expiry Date: 202	

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
GFX-EHP 605		605	Doch W	
GFX-EHP 655		655	104 10	A COLUMN TO SERVICE STATE OF THE PARTY OF TH
GFX-EHP 705		705		
GFX-EHP 765		765		(6.5

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification	
RGI-D 120		120			
RGI-D 140		140	The state of		
RGI-D 160		160	Reconstruction and augmentation of	Gy,	
RGI-D 180		180	congenital anomalies of	Carlo Pr	
RGI-D 200		200	the breast.		
RGI-D 220	DCI and Clind	220	Reconstruction of the breast following		
RGI-D 240	RGI gel-filled mammary implants:	240	subcutaneous mastectomy	Class III	
RGI-D 260	gel-filled smooth low	260	and other suitable mastectomy procedures or	implant	
RGI-D 280	profile	280	trauma.		
RGI-D 300		300	Combined breast and		
RGI-D 360		360	chest wall abnormalities.	5 (10)	
RGI-D 400		400	Replacement of implants for medical reasons.	FRU	

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Catalogue	Device Name	Weight (g)	Intended purpose per	Classification
Number		Model, Type	IFU .	
RGI-DH 140		140	151	
RGI-DH 160		160		
RGI-DH 180		180		100
RGI-DH 200		200	Reconstruction and augmentation of	
RGI-DH 220		220	congenital anomalies of	
RGI-DH 240		240	the breast. Reconstruction of the	
RGI-DH 260	RGI gel-filled	260	breast following	
RGI-DH 280	mammary implants: gel-filled smooth	280	subcutaneous mastectomy and other suitable	Class III implant
RGI-DH 300	high profile	300	mastectomy procedures or trauma.	implane
RGI-DH 320		320	Combined breast and	2 /
RGI-DH 340		340	chest wall abnormalities.	
RGI-DH 370		370	Replacement of implants for medical reasons.	E
RGI-DH 410		410	Tot medical reasons.	
RGI-DH 460		460		
RGI-DH 500		500		

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Catalogue	Device Name	Weight (g)	Intended purpose per	Classification
Number		Model, Type	IFU	
RGI-DEH 135		135	151	1
RGI-DEH 155		155		
RGI-DEH 175		179	3 7 1 1 1 1 1	100
RGI-DEH 195		195	Reconstruction and augmentation of	
RGI-DEH 215		215	congenital anomalies of	
RGI-DEH 235	RGI gel-filled	235	the breast. Reconstruction of the	
RGI-DEH 255		255	breast following	
RGI-DEH 275	mammary implants: gel-filled smooth	275	subcutaneous mastectomy and other suitable	Class III implant
RGI-DEH 295	extra high profile	295	mastectomy procedures or trauma.	implant
RGI-DEH 325		325	Combined breast and	2 /0
RGI-DEH 345		345	chest wall abnormalities.	
RGI-DEH 365		365	Replacement of implants for medical reasons.	E
RGI-DEH 395		395	Tot medical reasons.	
RGI-DEH 425		425		
RGI-DEH 465		465		

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
RGI-DEH 505		505	South W	
RGI-DEH 555		555	alone ap	A STREET
RGI-DEH 605		605	E SA	n Go
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		120		
XF1-145		145	The state of	
XF1-170		170	Reconstruction and augmentation of	Gy,
XF1-195		195	congenital anomalies of	Carlo Pr
XF1-235	9-cell Cogel	235	the breast.	
XF1-275	anatomical gel-filled	275	Reconstruction of the breast following	
XF1-300	mammary implants: Soft, form stable	300	subcutaneous mastectomy	Class III
XF1-350	cohesive gel-filled textured anatomical	350	and other suitable mastectomy procedures or	implant
XF1-390	– full height, low	390	trauma.	
	projection (CoGel)		Combined breast and chest wall abnormalities.	
XF1-430		430	Replacement of implants for medical reasons.	
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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
XF2-145		145	Reconstruction and	
XF2-170		170	augmentation of	
XF2-200	0 2011 Caral	200	congenital anomalies of the breast.	Tage .
XF2-230	9-cell Cogel anatomical gel-filled	230	Reconstruction of the	Carlo San
XF2-270	mammary implants:	270	breast following	
XF2-315	Soft, form stable cohesive gel-filled	315	subcutaneous mastectomy and other suitable	Class III
XF2-350	textured anatomical	350	mastectomy procedures or	implant
XF2-400	– full height,moderate projection	400	trauma.	
XF2-450	(CoGel)	450	Combined breast and chest wall abnormalities.	
XF2-505		505	Replacement of implants for medical reasons.	

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			/	
Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
XF3-170		170	Reconstruction and	
XF3-200		200	augmentation of	
XF3-235		235	congenital anomalies of the breast.	Tage .
XF3-280	9-cell Cogel	280	Reconstruction of the	Carlo San
XF3-320	anatomical gel-filled mammary implants:	320	breast following	
XF3-365	Soft, form stable	365	subcutaneous mastectomy and other suitable	Class III
XF3-405	cohesive gel-filled textured anatomical	405	mastectomy procedures or	implant
XF3-465	full height, high	465	trauma.	
XF3-515	projection (CoGel)	515	Combined breast and chest wall abnormalities.	
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		105	Reconstruction and	
XM1-135		135	augmentation of	
XM1-155	0 111	155	congenital anomalies of the breast.	
XM1-185	9-cell Cogel anatomical gel-filled	185	Reconstruction of the	
XM1-215	mammary implants:	215	breast following	
XM1-250	Soft, form stable cohesive gel-filled	250	subcutaneous mastectomy and other suitable	Class III
XM1-275	textured anatomical	275	mastectomy procedures or	implant
XM1-325	– moderate height,low projection	325	trauma.	
XM1-360	(CoGel)	360	Combined breast and chest wall abnormalities.	
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		130	Reconstruction and	
XM2-165		165	augmentation of	
XM2-185	0 2011 Caral	185	congenital anomalies of the breast.	
XM2-215	9-cell Cogel anatomical gel-filled	215	Reconstruction of the	
XM2-250	mammary implants:	250	breast following	
XM2-290	Soft, form stable cohesive gel-filled	290	subcutaneous mastectomy and other suitable	Class III
XM2-320	textured anatomical	320	mastectomy procedures or	implant
XM2-370	– moderate height,moderate projection	370	trauma.	
XM2-415	(CoGel)	415	Combined breast and chest wall abnormalities.	
XM2-445		445	Replacement of implants for medical reasons.	

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
XM3-155		155	Reconstruction and	
XM3-190		190	augmentation of	
XM3-215	0 11 1	215	congenital anomalies of the breast.	
XM3-260	9-cell Cogel anatomical gel-filled	260	Reconstruction of the	
XM3-300	mammary implants:	300	breast following	
XM3-335	Soft, form stable cohesive gel-filled	335	subcutaneous mastectomy and other suitable	Class III
XM3-375	textured anatomical	375	mastectomy procedures or	implant
XM3-440	– moderate height,high projection	440	trauma.	
XM3-485	(CoGel)	485	Combined breast and chest wall abnormalities.	
XM3-520		520	Replacement of implants for medical reasons.	

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

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			/	
Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
XL2-120		120	Reconstruction and	
XL2-145		145	augmentation of	
XL2-170	0	170	congenital anomalies of the breast.	
XL2-195	9-cell Cogel anatomical gel-filled	195	Reconstruction of the	
XL2-230	mammary implants:	230	breast following	
XL2-265	Soft, form stable cohesive gel-filled	265	subcutaneous mastectomy and other suitable	Class III
XL2-295	textured anatomical	295	mastectomy procedures or	implant
XL2-340	– low height,moderate projection	340	trauma.	
XL2-385	(CoGel)	385	Combined breast and chest wall abnormalities.	
XL2-425		425	Replacement of implants for medical reasons.	

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Catalague	Davisa Naw	Mainh (c)	Tubouded assured	Classifi and i
Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
XL3-160		160	Reconstruction and	Class III
XL3-175		175	augmentation of congenital anomalies of	implant
XL3-200	O coll Corol	200	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	
XL3-240	9-cell Cogel anatomical gel-filled	240		
XL3-275	mammary implants: Soft, form stable	275		
XL3-305	cohesive gel-filled	305		
XL3-350	textured anatomical — low height, high	350		
XL3-410	projection (CoGel)	410		
XL3-450		450		
XL3-480		480	for medical reasons.	5

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Classification	Intended purpose per IFU	Weight (g) Model, Type	Device Name	Catalogue Number
	Reconstruction and	165		IMP-MR 150
	augmentation of	190		IMP-MR 180
Tage .	congenital anomalies of the breast.	220		IMP-MR 210
	Reconstruction of the	255		IMP-MR 240
	breast following	278	Textured Impleo gel- filled mammary	IMP-MR 270
Class III	subcutaneous mastectomy and other suitable mastectomy procedures or	300	implants: soft, high	IMP-MR 300
implant		340	cohesive gel-filled textured – moderate	IMP-MR 330
	trauma.	365	range	IMP-MR 360
	Combined breast and	390		IMP-MR 390
	chest wall abnormalities.	430		IMP-MR 420
5 (1)	Replacement of implants for medical reasons.	480		IMP-MR 460

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

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		161		IMP-EHR 150
	The second	180		IMP-EHR 180
GOL	Reconstruction and	210		IMP-EHR 210
Class III implant	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.	235	Textured Impleo gel- filled mammary implants: soft, high cohesive gel-filled textured –extra high range	IMP-EHR 240
		260		IMP-EHR 270
		291		IMP-EHR 300
		332		IMP-EHR 330
		360		IMP-EHR 360
		400		IMP-EHR 390
		435		IMP-EHR 420
5 (1)		460		IMP-EHR 460
		520		IMP-EHR 520
QII		575		IMP-EHR 560
EM	ESS	620		IMP-EHR 620

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
IMP-SMR 150		165	Reconstruction and	2
IMP-SMR 180		190	augmentation of	
IMP-SMR 210		220	congenital anomalies of the breast.	GO
IMP-SMR 240	Smooth Impleo gel-	255	Reconstruction of the	Carrie Ser
IMP-SMR 270	filled mammary	278	breast following	
IMP-SMR 300	implants: soft, high	300	subcutaneous mastectomy and other suitable	Class III
IMP-SMR 330	cohesive gel-filled smooth – moderate	340	mastectomy procedures or	implant
IMP-SMR 360	range	365	trauma.	
IMP-SMR 390		390	Combined breast and chest wall abnormalities.	
IMP-SMR 420		430	Replacement of implants	
IMP-SMR 460		480	for medical reasons.	5 \

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Supplementary Information to CE 612851

Issued To: Nagor Limited

129 Deerdykes View Westfield Industrial Estate

Cumbernauld Glasgow G68 9HN

United Kingdom

Classification	Intended purpose per IFU	Weight (g) Model, Type	Device Name	Catalogue Number
		150		IMP-SHR 150
	Reconstruction and	180		IMP-SHR 180
GOL	augmentation of	210		IMP-SHR 210
(1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	congenital anomalies of the breast.	240		IMP-SHR 240
	Reconstruction of the	270		IMP-SHR 270
	breast following	300	Smooth Impleo gel-	IMP-SHR 300
Class III	subcutaneous mastectomy and other suitable	330	filled mammary implants: soft, high	IMP-SHR 330
implant	mastectomy procedures or	360	cohesive gel-filled	IMP-SHR 360
	trauma.	375	smooth – high range	IMP-SHR 390
	Combined breast and chest wall abnormalities.	425		IMP-SHR 420
5 (1)		460		IMP-SHR 460
	Replacement of implants for medical reasons.	505		IMP-SHR 520
RQ II	Jana	550		IMP-SHR 560

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Classification	Intended purpose per IFU	Weight (g) Model, Type	Device Name	Catalogue Number
		161		IMP-SEHR 150
	3686 - F	180		IMP-SEHR 180
Oce .	Reconstruction and	210		IMP-SEHR 210
Carrie Carr	augmentation of congenital anomalies of	235		IMP-SEHR 240
	the breast. Reconstruction of the	260	Smooth Impleo gel-	IMP-SEHR 270
		291		IMP-SEHR 300
Class III	breast following subcutaneous mastectomy	332	filled mammary implants: soft, high	IMP-SEHR 330
implant	and other suitable	360	cohesive gel-filled	IMP-SEHR 360
	mastectomy procedures or trauma.	400	smooth – extra high	IMP-SEHR 390
	Combined breast and chest wall abnormalities. Replacement of implants	435	range	IMP-SEHR 420
5 (0)		460		IMP-SEHR 460
		520		IMP-SEHR 520
RQII	for medical reasons.	575		IMP-SEHR 560
E	355	620		IMP-SEHR 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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