

# EC Design-Examination Certificate

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

**No.** CE 719612  
**Issued To:** **Nagor Limited**  
**129 Deerdykes View**  
**Westfield Industrial Estate**  
**Cumbernauld**  
**Glasgow**  
**G68 9HN**  
**United Kingdom**

In respect of:

**PERLE™ Sterile Smooth Opaque 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: **2020-06-10**

Date: **2020-06-10**

Expiry Date: **2024-05-26**

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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.

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## Supplementary Information to CE 719612

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
SOR-MR 165	PERLE™ 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
SOR-MR 190		190		
SOR-MR 220		220	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
SOR-MR 255		255		
SOR-MR 280		280		
SOR-MR 300		300	Combined breast and chest wall abnormalities.	
SOR-MR 340		340		
SOR-MR 365		364	Replacement of implants for medical reasons.	
SOR-MR 390		390		
SOR-MR 430		430		
SOR-MR 480		480		

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
SOR-HR 150	PERLE™ 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
SOR-HR 175		175		
SOR-HR 210		210	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
SOR-HR 235		235		
SOR-HR 270		270		
SOR-HR 300		300	Combined breast and chest wall abnormalities.	
SOR-HR 335		335		
SOR-HR 360		360	Replacement of implants for medical reasons.	
SOR-HR 380		380		
SOR-HR 425		425		
SOR-HR 460		460		
SOR-HR 505		505		
SOR-HR 550		550		

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Catalogue Number	Device Name	Weight (g) Model, Type	Intended purpose per IFU	Classification
SOR-EHR 160	PERLE™ gel-filled mammary implants: soft, high cohesive gel-filled smooth – extra high range.	160	Reconstruction and augmentation of congenital anomalies of the breast.	Class III Implant
SOR-EHR 180		180		
SOR-EHR 210		210	Reconstruction of the breast following subcutaneous mastectomy and other suitable mastectomy procedures or trauma.	
SOR-EHR 230		230		
SOR-EHR 260		260		
SOR-EHR 290		290	Combined breast and chest wall abnormalities.	
SOR-EHR 330		330		
SOR-EHR 360		360	Replacement of implants for medical reasons.	
SOR-EHR 400		400		
SOR-EHR 435		435		
SOR-EHR 460		460		
SOR-EHR 520		520		
SOR-EHR 575		575		
SOR-EHR 620		620		

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## Certificate History

Date	Reference Number	Action
Current	3091363	First issue.



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