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**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 719612

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
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. 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 lll Implant
SOR-MR 190		190		
SOR-MR 220		220		
SOR-MR 255		255		
SOR-MR 280		280		
SOR-MR 300		300		
SOR-MR 340		340		
SOR-MR 365		364		
SOR-MR 390		390		
SOR-MR 430		430		
SOR-MR 480		480		

First Issued: **2020-06-10** Date: **2020-06-10** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 719612

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
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. 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 lll Implant
SOR-HR 175		175		
SOR-HR 210		210		
SOR-HR 235		235		
SOR-HR 270		270		
SOR-HR 300		300		
SOR-HR 335		335		
SOR-HR 360		360		
SOR-HR 380		380		
SOR-HR 425		425		
SOR-HR 460		460		
SOR-HR 505		505		
SOR-HR 550		550		

First Issued: **2020-06-10** Date: **2020-06-10** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 719612

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
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. 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 lll Implant
SOR-EHR 180		180		
SOR-EHR 210		210		
SOR-EHR 230		230		
SOR-EHR 260		260		
SOR-EHR 290		290		
SOR-EHR 330		330		
SOR-EHR 360		360		
SOR-EHR 400		400		
SOR-EHR 435		435		
SOR-EHR 460		460		
SOR-EHR 520		520		
SOR-EHR 575		575		
SOR-EHR 620		620		

First Issued: **2020-06-10** Date: **2020-06-10** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 719612

Issued To:

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

Certificate History

Date	Reference Number	Action
Current	3091363	First issue.

First Issued: **2020-06-10** Date: **2020-06-10** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

Supplementary Information to CE 719612 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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

Date: 09 December 2021
Changes Approved:

Date	Reference Number	Action
09 December 2021	3566699	Reduction in Dry Heat Sterilisation Phase from 60 hours to 24 hours.

Inspiring trust for a more resilient world.

09 December 2021

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related CE 719612 specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 719612	93/42/EEC Annex II Section 4	3566699	The Sterilisation Phase of the Dry Heat Sterilisation Process reduced from 60 hours to 24 hours.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl