EC Design-Examination Certificate

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

No. **CE 633491**

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

In respect of:

Integrated valve tissue expanders (IVTE) for use in the breast.

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: **2016-12-08** Date: **2020-05-27** Expiry Date: **2024-05-26**

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
TE-XF3 300 -TE-XF3 800	Integrated Valve Tissue Expander	Anatomical Textured - Full Height, High Projection	• Reconstruction of the breast following subcutaneous mastectomy and mastectomy procedures or trauma. • Breast underdevelopment and combined breast and chest wall abnormalities • Scar/defect revision.	Class III Implant

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
TE-XM3 200 -TE-XM3 700	Integrated Valve Tissue Expander	Anatomical Textured - Moderate Height High Projection	• Reconstruction of the breast following subcutaneous mastectomy and mastectomy procedures or trauma. • Breast underdevelopment and combined breast and chest wall abnormalities • Scar/defect revision	Class III Implant
TE-XL3 200 -TE-XL3 500	Integrated Valve Tissue Expander	Anatomical Textured - Low Height, High Projection	• Reconstruction of the breast following subcutaneous mastectomy and mastectomy procedures or trauma. • Breast underdevelopment and combined breast and chest wall abnormalities • Scar/defect revision	

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Certificate History

Date	Reference Number	Action
08 December 2016	10154660	Initial issue (upclassification to Class III).
24 January 2017	10166364	Review of manufacturing solvent change.
22 February 2019	7779519	Traceable to NB 0086
Current	3045749	Certificate renewal. Administrative update to supplementary device table. Addition of GC Aesthetics (Management) Limited Suite 601, Q House, Furze Road, Sandyford Industrial Estate Dublin 18 Ireland as EU Authorized Representative.

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