



EC Design-Examination Certificate

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

№ 01712

No.

CE 645520

Issued To:

**Eurosilicone SAS
Z.I de la Peyrolière
B.P. 68
Apt Cédex
84402
France**

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 November 2016**

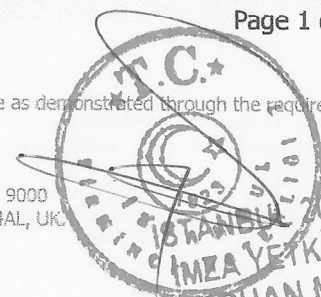
Date: **17 February 2017**

Expiry Date: **31 October 2021**

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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.



20. NOTERİ
İMZA YETKİLİ KATİP
SERHAN MANDACI



EC Design-Examination Certificate

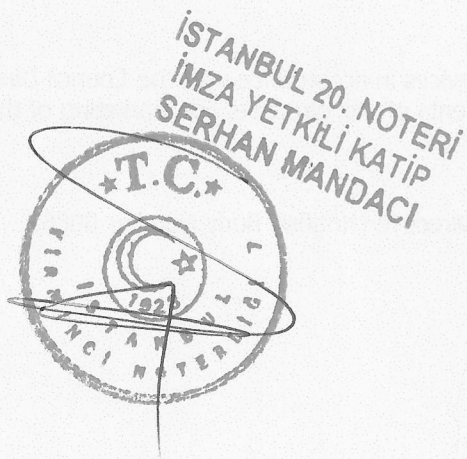
Supplementary Information to CE 645520

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Integrated Valve Tissue Expanders (IVTE)

IVTE Product Codes	Tissue Expander Description
TE-F3 300 – TE-F3 800	Anatomical Textured – Full Height, High Projection
TE-M3 200 - TE-M3 700	Anatomical Textured – Moderate Height, High Projection
TE-L3 200 - TE-L3 500	Anatomical Textured – Low Height, High Projection



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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EC Design-Examination Certificate

Supplementary Information to CE 645520

№ 017112

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Certificate History

Date	Reference Number	Action
01 November 2016	10159701	Initial issue (upclassification to Class III).
17 February 2017	10167651	Review of manufacturing solvent change.

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