

# EC Certificate - Full Quality Assurance System

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

**No.****CE 669612****Issued To:**

**Euromi Biosciences  
Zoning Industriel des Plenesses  
11 rue des nouvelles technologies  
B-4821 Andrimont  
Belgium**

In respect of:

**Design, development and manufacture of silicone breast implants**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II 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: **2021-04-02**

Date: **2021-04-02**

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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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## Supplementary Information to CE 669612

Issued To:

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Number	Device Name	Intended purpose per IFU
<b>Class III</b>		
---	Round shaped textured and smooth silicone gel breast implants.	See CE 669619.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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**Belgium**

### Subcontractor:

### Service(s) supplied

NuSil Technology Inc.  
 1050 Cindy Lane  
 Carpinteria  
 California  
 USA

**Crucial Supplier**

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## Certificate History

Certificate No: **CE 669612**  
Date: **2021-04-02**  
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Date	Reference Number	Action
Current	8694760	First issue.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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