



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

Gay C Stade

First Issued: **2021-04-02** Date: **2021-04-02** Expiry Date: **2024-05-26**

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Page 1 of 2

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

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

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Page 2 of 2

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List of Significant Subcontractors

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

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Subcontractor:

Service(s) supplied

Crucial Supplier

NuSil Technology Inc. 1050 Cindy Lane Carpinteria California USA

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669612**Date: **2021-04-02**

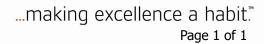
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Date	Reference Number		Action
Current	8694760	First issue.	The state of the s



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