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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 669612

Issued To:

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Zoning Industriel des Plenesses
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Number	Device Name	Intended purpose per IFU
Class III		
---	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:

Certificate No:	**CE 669612**
Date:	**2021-04-02**
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Subcontractor:	**Service(s) supplied**
Euromi Biosciences France Actipôle 2, Avenue de la Solette Sailly-Lez-Cambrai 59554 France	**Design** **Development** **Manufacture**
NuSil Technology Inc. 1050 Cindy Lane Carpinteria California USA	**Crucial Supplier**

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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
02 April 2021	8694760	First issue.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
03 August 2022	3447299	Addition of critical subcontractor Euromi Biosciences France for design, development, and manufacture of CEREFORM®, CREAFORM®, and EUROMI BIOSCIENCES round silicone gel-filled breast implants

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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Inspiring trust for a more resilient world.

03 August 2022

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

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 MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 669612	93/42/EEC Annex II excluding Section 4	3447299	Addition of critical subcontractor Euromi Biosciences France for design, development, and manufacture of CEREFORM®, CREAFORM®, and EUROMI BIOSCIENCES round silicone gel-filled breast implants

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,

Graeme Tunbridge
Senior Vice President, Medical Devices

By Royal Charter

SUSTAINABLE DEVELOPMENT GOALS