EC Certificate - Full Quality Assurance System

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

No. **CE 645455**

Issued To: **Eurosilicone SAS**
Z.I de La Peyrolière
B.P. 68
APT Cédex
84402
France

In respect of:

The design, development and manufacture of sterile silicone gel filled implants, solid silicone implants, integrated and remote valve tissue expanders and associated sizing devices.

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: **2016-08-05** Date: **2021-05-14** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 645455

Issued To:

Eurosilicone SAS
Z.I de La Peyrolière
B.P. 68
APT Cédex
84402
France

Number	Device Name	Intended purpose per IFU
Class III		
---	Integrated Valve Tissue Expanders for use in the breast	See CE 645520
---	Silicone Gel Pre-Filled Mammary Implants	See CE 645522
IIb		
35261	Chin Implants	For cosmetic or reparative surgery
35277	Testicular Implants	For cosmetic or reparative surgery
63392	Calf Implants	For cosmetic or reparative surgery
45187	Remote Valve Tissue Expanders	For cosmetic or reparative surgery
IIa		
MD 0106	Mammary Sizers	---

First Issued: **2016-08-05** Date: **2021-05-14** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 645455**
Date:	**2021-05-14**
Issued To:	**Eurosilicone SAS** **Z.I de La Peyrolière** **B.P. 68** **APT Cédex** **84402** **France**

Subcontractor:	**Service(s) supplied**
Biosil Limited 127 Deerdykes View Westfield Industrial Estate Cumbernauld, Glasgow G68 9HN United Kingdom	**Finished Device Supplier**
Nusil Technology 1050 Cindy Lane Carpinteria 93013 California United States	**Crucial Supplier**
Sterlab 485 avenue de Berlin Allée des Jacarandas Parc d'activités du Plateau de Signes 83870 SIGNES France	**ETO Sterilization**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 645455**
Date: **2021-05-14**
Issued To: **Eurosilicone SAS**
Z.I de La Peyrolière
B.P. 68
APT Cédex
84402
France

Date	Reference Number	Action
05 August 2016	8436882	First issue. Transfer from another Notified Body.
21 December 2018	9671093	Sterlab facility relocation to 485 Avenue de Berlin, Signes, France.
13 February 2019	8711246	Traceable to NB 0086.
05 August 2020	3054448	Certificate renewal. Gluteus Implants and Malar & Nasal Implants removed from the device schedule. PROGRESS removed as a critical subcontractor. Device schedule table added to the Supplementary Information page.
14 May 2021	3423521	Removal of Class III Remote Valve Tissue Expanders (for use in the breast) from the Supplementary Table.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
31 January 2022	3615741	Removal of Integrated Valve Tissue Expanders for use in breast.

Inspiring trust for a more resilient world.

31 January 2022

Eurosilicone SAS
Z.I de La Peyrolière
B.P. 68
APT Cédex
84402
France

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 645455	93/42/EEC Annex II excluding Section 4	3615741	Removal of Class III Integrated Valve Tissue Expanders (IVTE) for use in the breast, from the supplementary table of the certificate.

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,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl