



# EC Certificate - Full Quality Assurance System

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

**№ 017.10**

**No.** **CE 645455**  
**Issued To:** **Eurosilicone SAS**  
**Z.I de La Peyrolière**  
**B.P. 68**  
**APT Cédex**  
**84402**  
**France**

In respect of:

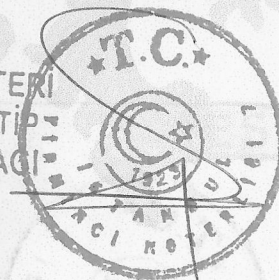
**The design, development and manufacture of sterile silicone gel filled implants, solid silicone implants, integrated and remote valve tissue expanders and associated sizing devices.**

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 0086):

Frank Lee, EMEA Compliance & Risk Director

İSTANBUL 20. NOTERİ  
İMZA YETKİLİ KATİP  
SERHAN MANDACI



First Issued: **05 August 2016**

Date: **05 August 2016**

Expiry Date: **09 August 2020**

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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.



## EC Certificate - Full Quality Assurance System

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### List of Significant Subcontractors

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

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**84402**  
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**Subcontractor:**

**Service(s) supplied**

Bosil Limited  
127 Deerdykes View  
Westfield Industrial Estate  
Cumbernauld, Glasgow  
G68 9HN  
United Kingdom

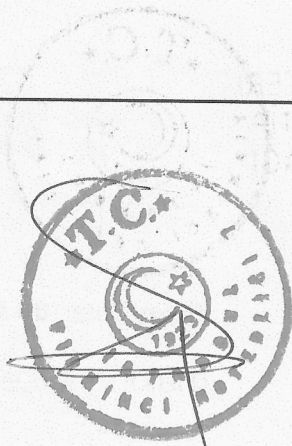
**Finished Device Supplier**

Nusil Technology LLC  
1060 Cindy Ln  
Carpinteria  
California  
93013  
USA

**Crucial Supplier**

PROGRESS  
ZI des Bourguignons  
APT  
84400  
France

**Manufacture**



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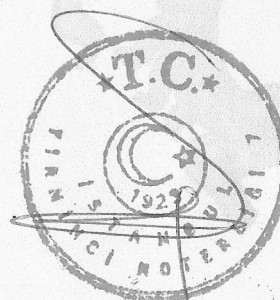
**Subcontractor:**

**Service(s) supplied**

Sterlab  
2720 Ch. St-Bernard  
06224 Vallauris  
France

**ETO Sterilization**

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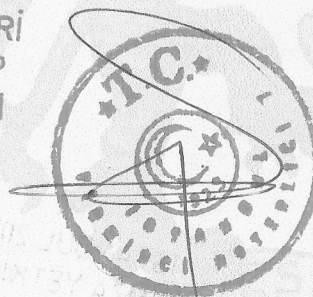


## EC Certificate - Full Quality Assurance System Certificate History

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France**

Date	Reference Number	Action
05 August 2016	8436882	First issue. Transfer from another Notified Body.

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