

# EC Certificate - Full Quality Assurance System

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

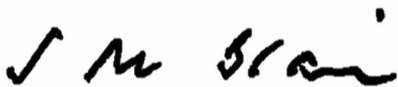
**No.** CE 674184  
**Issued To:** **Euromi SA**  
**Zoning Industriel de Lambermont**  
**151, rue des Ormes**  
**Verviers**  
**4800**  
**Belgium**

In respect of:

**Design, development and manufacture of non-sterile liposuction equipment, pneumatic hand pieces (without cannula), infiltration cannulae, aspiration cannulae and sterile fat cell collection and re-injection kit for therapeutic treatment of lymphedema and lipomatosis and adipocyte grafting for reinjection during reconstruction surgery.**

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):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2017-11-30**

Date: **2017-11-30**

Expiry Date: **2020-03-08**

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Page 1 of 1

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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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:

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Beldico SA Rue Andre Feher, 3 Zoning de Aye Marche-en-Famenne 6900 Belgium	<b>Manufacture</b>
Cerecare 780 Rue Blaise Pascal Proville 59267 France	<b>Regulatory Compliance</b>
COJEMA 8A, rue du Pont Rocleng-sur-Geer B-4690 Belgium	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Electronique du Mazet Zone Artisanale - Route de Tence Mazet Saint Voy 43520 France	<b>Manufacture</b>
FGC Indústriae Comércio De Componentes Mecânicos LTDA AV. Prof. Silvina Borges Graciosa Nº 57 Valença - RJ Brasil	<b>Manufacture</b>
Mertens Plastique S.A Zoning des Plenesses 3 Rue des Waides Thimister-Clermont 4890 Belgium	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Precical 33 Rue du Tilleul Hermalle-sous-Argenteau 4681 Belgium	<b>Manufacture</b>
Sogex EREM SA Rue des Forgerons, 29 Marcinelle 6001 Belgium	<b>Manufacture</b>
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 B-4800 Verviers Belgium	<b>ETO Sterilization</b>

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# EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
Current	8742615	First Issue, Transfer from another Notified Body.

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Page 1 of 1

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