By Royal Charter

# 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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# 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:

| | |
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| Certificate No: | **CE 674184** |
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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Beldico SA<br>Rue Andre Feher, 3<br>Zoning de Aye<br>Marche-en-Famenne<br>6900<br>Belgium | **Manufacture** |
| Cerecare<br>780 Rue Blaise Pascal<br>Proville<br>59267<br>France | **Regulatory Compliance** |
| COJEMA<br>8A, rue du Pont<br>Roclenge-sur-Geer<br>B-4690<br>Belgium | **Manufacture** |

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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Electronique du Mazet<br>Zone Artisanale - Route de Tence<br>Mazet Saint Voy<br>43520<br>France | **Manufacture** |
| FGC Indústriae Comércio De<br>Componentes Mecânicos LTDA<br>AV. Prof. Silvina Borges Graciosa<br>N° 57 Valença - RJ<br>Brasil | **Manufacture** |
| Mertens Plastique S.A<br>Zoning des Plenesses<br>3 Rue des Waides<br>Thimister-Clermont<br>4890<br>Belgium | **Manufacture** |

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

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 674184**

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