

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 des Plenesses
11 Avenue des nouvelles technologies
Andrimont
B-4821
Belgium**

In respect of:

Design, development and manufacture of non-sterile liposuction equipment, pneumatic hand pieces (without cannula), infiltration cannulae, aspiration cannulae, lipofilling 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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-11-30**Date: **2020-03-06**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.

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Supplementary Information to CE 674184

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Number	Device Name	Intended purpose per IFU
Class IIa		
SMD1104	Non-sterile liposuction equipment	N/A
SMD1104	Non-sterile pneumatic handpiece	N/A
SMD0102	Non-sterile infiltration cannulae	N/A
SMD0102	Non-sterile aspiration cannulae	N/A
SMD0102	Non-sterile lipofilling cannulae	N/A
SMD0102	Sterile fat cell collection and re-injection kit	N/A

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