By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 779914 R000

Manufacturer: Euromi SA

Address:
Zoning Industriel des Plenesses
Avenue des nouvelles technologies
Andrimont
11 B-4821
Belgium

Single Registration Number: BE-MF-000014212

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-08-27**

Current Issue Date: **2025-08-27**

Starting Validity Date: **2025-08-27**

Expiry Date: **2030-08-26**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Liposuction Systems	Medical intended purpose: • Lipoinfiltration: Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid for the treatment of lipomatosis, lymphoedema or during breast reconstruction procedures. • Liposuction: The removal of tissue and/or fluid from the body for the treatment of lipomatosis, lymphoedema or during breast reconstruction/reduction procedures.
Liposuction Systems, Annex XVI	Non-medical intended purpose: • Lipoinfiltration: Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid during aesthetic procedures. • Liposuction: The removal of tissue and/or fluid from the body during aesthetic procedures.
Surgical Equipment for Liposuction Systems	Medical intended purpose: • Lipoinfiltration: Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid for the treatment of lipomatosis, lymphoedema or during breast reconstruction procedures. • Liposuction: The removal of tissue and/or fluid from the body for the treatment of lipomatosis, lymphoedema or during breast reconstruction/reduction procedures. • Lipofilling: Introduction of autologous adipose tissues during breast reconstruction procedures.
Surgical Equipment for Liposuction Systems, Annex XVI	Non-medical intended purpose: • Lipoinfiltration: Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid during aesthetic procedures. • Liposuction: The removal of tissue and/or fluid from the body during aesthetic procedures.

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Liposuction System Cannulas	Class IIa
Liposuction System Cannulas	Class IIa, Annex XVI
Surgical Instruments for Liposuction Systems	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3776293	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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