

EUROMI BIOSCIENCES statement regarding commercial name "CEREFORM®"

Entity name: **EUROMI BIOSCIENCES**

Head quarter address: 11 Rue des Nouvelles Technologies, B-4821, Andrimont, BELGIUM

Statement:

To whom it may concern,

Euromi Biosciences has been manufacturing silicone gel filled breast implants since 2016. These implants are classified as class III implantable medical device in accordance with both the EU Medical Device Directive 93/42/EEC and Medical Device Regulation 2107/745.

Euromi Biosciences breast implants have been CE-certified by the notified body BSI (CE No. 2797) since April 2, 2021. The company has held ISO 13485 certification (International quality standard for medical devices – Quality management systems – Requirements for regulatory purposes) since August 6, 2020.

These implants are marketed under the name **CEREFORM®**, a brand formerly owned by the company CEREPLAS.

We chose to retain the **CEREFORM®** name due to its long-standing reputation for reliability and excellence among healthcare professionals worldwide, despite a temporary CE mark suspension in 2014.

In response to the suspension, CEREPLAS voluntarily recalled the products, even though there were no health risks. For the implants already on the market and used in patients, CEREPLAS provided full documentation confirming their safety, as supported by the French health authority (ANSM, National Agency for the Safety of Medicines and Health Products)¹.

Euromi Biosciences acquired the rights to the **CEREFORM®**, and manufacturing process, and implemented an improved sterilization method using dry heat for enhanced product safety.

With over five years of manufacturing experience, **Euromi Biosciences** continues to leverage the knowledge gained from CEREPLAS while maintaining strict safety and quality standards for customers.

Euromi Biosciences is part of a medical device group with more than 30 years of experience in plastic and aesthetic surgery. Our group also includes:

- CERECARE (France): Specialists in compression garments and silicone dressings
- EUROMI (Belgium): Leaders in liposuction, lipofilling, and mesotherapy equipment

For any further information on our products, please contact us at: info@euromi-biosciences.com

David LELEU

CEO, Euromi Biosciences

¹ ANSM, Breast implants from the company CEREPLAS – Suspension of marketing and product withdrawal – Updated Information Notice dated 17/04/2014: <https://archive.ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Implants-mammaires-de-la-societe-CEREPLAS-Suspension-de-la-mise-sur-le-marche-et-retrait-des-produits-Point-d-Information-actualise-le-17-04-2014>