



Salute al naturale

Declaration of Conformity

Sakura Italia Srl, located in Via Marziale Cerutti, 90/c – 25017 Lonato Del Garda (BS) – Italy,
Manufacturer of the medical device **Clogin Elle Vaginal Ovules**

Destined to be used in humans as coadjuvant in the prevention and treatment of phlogistic, infectious and dystrophic vaginal disorders,

DECLARES

under its own responsibility, that the medical device Clogin Elle Vaginal Ovules meets all the essential requirements required by Annex I of the Medical Device Directive 93/42/EEC.

It guarantees and declares the following:

- the device meets the applicable provisions of Directive 93/42/EEC and subsequent amendments (Dir. 2007/47/CE), incorporated into national legislation with Legislative Decree no. 46/97 and subsequent amendments including Legislative Decree no. 37/2010;
- the device belongs to Class IIa according to Rule n°5 of Annex IX - Directive 93/42/CEE, (implemented in Italy with Legislative Decree 24 February 1997, n. 46, and subsequent modifications);
- the device complies with the essential requirements and the provisions of Directive 93/42/EEC as per Clogin Elle Vaginal Ovules technical dossier current version;
- the device is manufactured in accordance with the Quality System that meets the requirements of Annex V of the aforementioned Legislative Decree, as per Certificate n. EPT 0477.MDD.19/3241.1 deadline 2024-04-08, issued by EUROFINS PRODUCT TESTING ITALY, Via Cuornè 21, 10156 Turin - Notified Body n. 0477.

The manufacturer also declares to have established and to maintain a suitable procedure to guarantee the post-marketing surveillance required by Directive 93/42 / EEC and subsequent amendments.

Lonato del Garda (BS), 16/05/2022

Gabriela Bandrés Ardanaz
Legal representative

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Sakura Italia Srl

Società soggetta ad attività di direzione e coordinamento di LABORATORIOS CINFA S.A.

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