MD-P-02-01 Rev.4 del 05.2024

EC Declaration of conformity

with essential requirements of annex I of Directive 93/42/CEE as defined by Annex VII of the said directive 93/42/CEE

The present writer **EKUBERG Pharma srl** with registered office at Via Tito Schipa 6, Carpignano Salentino (LE), Italy, in quality of Manufacturer of the device called

Product name	DERMOXEN BACTOR VAGINAL OVULES
Format and size	3 ovules of 2 grams

declares under its own responsibility that the Medical Device referred above satisfies the dispositions applicable in Directive 93/42/CEE, and its further integrations and modifications, including the norms of acknowledgment in the national legislation of communitarian directives on Medical Devices.

For this purpose, the present writer guarantees and declares under its own responsibility what follows:

- The aforementioned device shall be implemented in accordance with the provisions of Directive 93/42/EEC and s.m.i., in accordance with the provisions of Annexes V + VII (Certificate n° IT-301068-3, deadline 26.05.2024, issued by the Notified Body Bureau Veritas Italia (Notified Body n° 1370)– Viale Monza 347, 20126 Milan;
- About the aforementioned device Ekuberg Pharma has requested a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement n. 7250833, in accordance with Section 4.3, second subparagraph of Annex VII of MDR with Bureau Veritas for the transition of the product in MDR Regulation 2017/745; therefore in accordance with EU Regulation 2023/607, the validity of this Declaration of Conformity is extended until 31.12.2028, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.
- The device referred to above shall be considered as belonging to Class II(a) on the basis of Rules 4 and 5, Annex IX to Directive 93/42/EEC and subsequent.
- All documentation relating to this device shall be stored in the Technical File of product and shall be kept for a period of at least 5 years from the date of last manufacture of the product;
- All stages of implementation of the aforementioned device shall comply with the requirements set out in the Management System for Quality of the Company in accordance with annex V to the abovementioned Directive;
- This Management System for Business Quality has been implemented in accordance with the requirements specified in EN ISO 13485:2021 standard;
- Ekuberg Pharma S.r.l. it has put in place a procedure to ensure the after-sales surveillance of the medical device placed on the market according to MDR 2017/745 disposal.
- The validity of this declaration shall be subject to the validity of the EC certificate No IT-301068-3 referred to above, unless significant changes have been made to the product or its implementation process.

Therefore, it is declared that the device is in compliance with what established by 93/42/CEE Directive and its further modifications and/or integrations, Eu Regulation 2023/607 and that it will be sold with CE mark according to what defined by article 17 of 93/42/CEE Directive.

CE

Carpignano Salentino (LE) – Italy
Place of issue

Responsible person Medical Device Ekuberg Pharma
Dr. Davide Carati

CEO Ekuberg Pharma
Pantaleo GIANNUZZI