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	LECOXEN CREAM
Format and size	□ 15ml **x** 30ml □75ml

declares under its own responsibility that

- It satisfies the essential requirements in Annex I of the 93/42 European Directive;
- It is to be considered as belonging to Class IIa, according to Annex IX, chapter III (classification), point 1.4, rule 4, third hyphen, of the 93/42 European Directive;
- It is marketed in un-sterile packaging, is not a measuring device, is not destined to clinical investigations;
- It does not contain any pharmacologically or biologically active substances and it doesn't include any tissues of animal origin and/or human blood or tissue derivative nor nanomaterials;
- It fully complies with the prescription of the 93/42 European Directive.

The manufacturer commits itself to prepare, keep and make available for the competent authorities the conformity declaration and the technical documents to support the quality of the manufacturing process as described in the Annex V and Annex VII of 93/42 European Directive for a period of five years from the last manufacturing date of the product. Furthermore the manufacturer commits itself to implement and keep update a quality system for the post-marketing evaluation and surveillance of the device and of its effects, in order to be able ti perform suitable corrective actions. The procedure of evaluation of this device is made according to the Annex V + VII of the 93/42 European Directive and following updates.

The compliance was evaluated by Certiquality srl, CE 0546, Via Gaetano Giardino 4, Milan, Italy with the certificate n. 23469 with the expiring date 26/05/2024.

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.

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.

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.

Carpignano Salentino (LE) – Italy

Responsible person Medical Device Ekuberg Pharma
Dr. Davide Carati

CEO Ekuberg Pharma
Pantaleo GIANNUZZI