URSAPHARM Arzneimittel GmbH
Industriestraße 35
66129 SAARBRÜCKEN
GERMANY

DOC_HYLO PARIN_EU_2024-05-29

DECLARATION OF CONFORMITY

We hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by the "EC Certificate", **No.: 2018308CE01**, first issued on **19/08/2002,** revised on **12/04/2016** and reissued on **29/09/2017** and the "Design Examination Certificate", **No.: 2018308DE01.**, first issued on **11/04/2016 and reissued on 29/09/2017**, both delivered by **DEKRA Certification B.V. – Meander 1051 - 6825 MJ ARNHEM, THE NETHERLANDS, Notified Body Identification Number 0344**, and conform to the required technical documentation, in accordance with Annex II including (4) for the class III products of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class III, meet the provisions of the EC-Directive, which apply to them.

This declaration based on the application of the Quality System approved for the manufacture and final inspection of the products concerned **(2018308CE01)**, in accordance with Annex II excluding (4) of the EC-Directive. The conformity of the production quality assurance set out in Annex II, is described in the said CE Marking of Conformity Certificate, issued and delivered by **DEKRA Certification B.V.** and the confirmation on extension of validity in accordance with Regulation (EU) 2023/607 regarding the transitional provisions for legacy devices.

This declaration is supported by the Quality System certification based on the harmonized standard EN ISO 13485:2016, Quality System Certificate with registration number **SX 1010771-1**, issued on **01/09/2023** are delivered by **TÜV Rheinland LGA Product GmbH**.

This Declaration of Conformity covers **sterile eye care products** as specified in the product list belonging to this declaration, and is only valid in connection with a batch-specific **Certificate of Compliance** for all products concerned bearing the CE marking and manufactured at the following site:

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The manufacturer herewith confirms that the device fulfils the conditions set out in REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745.

This DoC is valid until 2027-12-31

Anette Hornberger
Head of Regulatory Affairs

Annex: Product list