URSAPHARM Arzneimittel GmbH
Industriestraße 35
66129 SAARBRÜCKEN
GERMANY

DOC_HYLO PARIN_EU_2023-04

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 excluding (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, in accordance with Annex II excluding (4) of the EC-Directive. The conformity of the production quality assurance set out in Annex II excluding (4), is described in the said CE Marking of Conformity Certificate, issued and delivered by **DEKRA Certification B.V.** and the confirmation in accordance with article 97 issued and delivered by the competent authority **Landesamt für Umwelt- und Arbeitsschutz.**

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 **28/02/2023** 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:

URSAPHARM Arzneimittel GmbH
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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

Annex to the Declaration of Conformity (Product list) DOC_HYLO PARIN_EU_2023-04

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PRODUCT LIST

This product list belongs to the Declaration of Conformity identified by **DOC_HYLO PARIN_EU_2023-04** and specifies the CE marked product concerned that **URSAPHARM Arzneimittel GmbH** intends to distribute the device in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC and Regulation (EU) 2023/607 of 15 March 2023 amending Regulation (EU) 2017/745. The following list identifies the products by **name, dosage form, and article-number**.

Trade Name	**Dosage form**	**Country**	**Article no. finished product**
HYLO PARIN	eye drops, solution	Austria	55.0702 - 10 ml
HYLO PARIN	eye drops, solution	BE/LU/NL	38.2548– 10 ml
HYLO PARIN	eye drops, solution	Czech Republic/ Slovak Republic	55.0150 - 10 ml
HYLO CORNEAL	eye drops, solution	France	55.0795 - 10 ml
HYLO PARIN	eye drops, solution	Germany	38.1605 – 10 ml 55.0209 – 10 ml sample not for sale
HYLO PARIN	eye drops, solution	Poland	38.2524 – 10 ml
HYLO-PARIN	eye drops, solution	Portugal	55.1237 – 10 ml 55.1238- 10 ml sample not for sale
HYLO PARIN	eye drops, solution	Romania	55.1958 – 10 ml 55.1959 – 10 ml sample not for sale
HYLO-PARIN	eye drops, solution	Spain	55.0807 – 10 ml 55.0808 – 10 ml sample not for sale