

**URSAPHARM Arzneimittel GmbH**  
**Industriestraße 35**  
**66129 SAARBRÜCKEN**  
**GERMANY**

**DOC\_HYLO CARE®\_EU\_2024-10-02**

## **DECLARATION OF CONFORMITY**

We hereby declare that the distributed CE marked product, specified in the annexed product list, conform to the product covered by the "CE Marking of Conformity Certificate", **Registration No.: HD 60151576 0001, CE0197**, issued on **05/11/2020** and delivered by **TÜV Rheinland LGA Products GmbH – Tillystraße 2 - D-90431 Nürnberg, Notified Body Identification Number 0197**, and conform to the required technical documentation, in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC concerning medical devices.

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

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the product concerned, in accordance with Annex II of the EC-Directive. The conformity of the production full quality assurance system set out in Annex II, is described in the said CE Marking of Conformity Certificate, issued and delivered by **TÜV Rheinland LGA Product GmbH**.

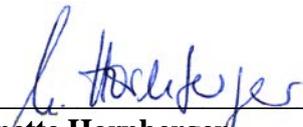
This declaration is supported by the Quality System certification based on the harmonized standard EN ISO 13485:2016, Quality System Certificate with registration number **SX 1010771-1**, issued on **25/09/2024** are delivered by **TÜV Rheinland LGA Product GmbH**.

This Declaration of Conformity covers **the design/development and manufacture of sterile eye drops** 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 2028-12-31**

  
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**Anette Hornberger**  
**Head of Regulatory Affairs**

Annex: Product list

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## PRODUCT LIST

This product list belongs to the Declaration of Conformity identified by **DOC\_HYLO CARE®\_EU\_2024-10-02** 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	Country	Art. no. finished product	Pack size
HYLO CARE®	Austria	55.0730 55.1511	10 ml 10 ml (FCB)
HYLO-CARE®	BE/LU/NL	38.2354	10 ml
HYLO CARE®	CZ/SK/HU/SI	38.2355	10 ml
HYLO CARE®	DK/FI/IS/NO/SE	55.2547	10 ml
HYLO-CARE®	EE/LT/LV	38.2638 55.2240	10 ml 5 ml – sample not for sale
HYLO CARE®	France	55.0796	10 ml
HYLO CARE®	Germany	38.2351 55.1504 55.1503 55.0207 38.2352 55.2260	10 ml 10 ml (FCB) – sample not for sale 10 ml (FCB) 10 ml – sample not for sale 2 x 10 ml 5 ml – sample not for sale
HYLO-CARE	Ireland	38.2821 55.0249	7.5 ml 7.5 ml – sample not for sale
HYLO CARE®	Italy	55.1532 55.2252	10 ml 5 ml – sample not for sale
HYLO CARE®	Poland	38.2357 55.2240	10 ml 5 ml – sample not for sale
HYLO-CARE®	Portugal	55.1232 55.1233 55.2398	10 ml 10 ml – sample not for sale 5 ml – sample not for sale
HYLO CARE®	Romania	55.1956 55.2480	10 ml 5 ml – sample not for sale
HYLO-CARE®	Switzerland	38.2356 55.1686 55.2334	10 ml 10 ml – sample not for sale 5 ml – sample not for sale
HYCOSAN® PLUS	United Kingdom	38.2754 55.0359	7.5 ml 7.5 m – sample not for sale
HYLO-CARE	United Kingdom	38.2813 55.0254	10 ml 7.5 ml – sample not for sale