

URSAPHARM Arzneimittel GmbH  
Industriestraße 35  
66129 SAARBRÜCKEN  
GERMANY

DOC\_HYLO-GEL\_EU\_2020-04

## 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 60132728 0001, CE0197**, issued on **28/11/2018** 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 standards ISO 9001:2015 and EN ISO 13485:2016, Quality System Certificates with registration numbers: **01 100 1810001**, issued on **21/02/2020** and **SX 60146387 0001**, issued on **07/02/2020** 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:

URSAPHARM Arzneimittel GmbH  
Industriestraße 35  
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Saarbrücken, April 2020

Annex: Product list

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Anette Hornberger  
Head of Regulatory Affairs

**URSAPHARM Arzneimittel GmbH**  
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**66129 SAARBRÜCKEN**  
**GERMANY**

## PRODUCT LIST

This product list belongs to the Declaration of Conformity identified by **DOC\_HYLO-GEL\_EU\_2020-04** and specifies the CE marked product concerned that **URSAPHARM Arzneimittel GmbH** intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC concerning medical devices. The following list identifies the products by **name, dosage form, and article-number**.

Trade Name	Country	Article no. finished product	Pack size
HYLO® GEL	Austria	55.0735 55.0737	10 ml 2 x 10 ml
HYLO® GEL	Belgium	38.2551 BE 39.2671 BE	10 ml 2 ml – sample not for sale
HYLO® GEL	Czech Republic	38.2588 CZ	10 ml
HYLO®-GEL	Denmark	38.2594 DK 55.1114 DK	10 ml 10 ml – sample not for sale
HYLO-GEL	Estonia	55.0749 EE	10 ml
HYLO®-GEL	Finland	38.2594 FI 55.1114 FI	10 ml 10 ml – sample not for sale
HYLO CONFORT® PLUS	France	55.0793 55.0806	10 ml 10 ml – sample not for sale
HYLO® GEL	Germany	38.2433 55.0208 38.2829	10 ml 10 ml – sample not for sale 2 x 10 ml
HYLO® GEL	Greece	55.1017	10 ml
HYLO®-FORTE	Ireland	38.2819 55.0218	7.5 ml 7.5 ml – sample not for sale
HYLO® GEL	Italy	55.1531	10 ml
HYLO-GEL	Latvia	55.0749 LV	10 ml
HYLO-GEL	Lithuania	55.0749 LT	10 ml
HYLO® GEL	Luxemburg	38.2551 LU 39.2671 LU	10 ml 2 ml – sample not for sale
HYLO-GEL	Malta	55.0949	10 ml
HYLO® GEL	Netherlands	38.2551 NL 39.2671 NL	10 ml 2 ml – sample not for sale
HYLO®-GEL	Norway	38.2594 NO 55.1114 NO	10 ml 10 ml – sample not for sale
HYLO® GEL	Poland	38.2517	10 ml
HYLO® GEL	Portugal	55.1230 55.1231	10 ml 10 ml – sample not for sale
HYLO®-GEL	Romania	55.1140 55.1403	10 ml 10 ml – sample not for sale

<b>Trade Name</b>	<b>Country</b>	<b>Article no. finished product</b>	<b>Pack size</b>
HYLO® GEL	Slovak Republic	38.2588 SK	10 ml
HYLO-GEL	Spain	55.0594 55.0595	10 ml 10 ml – sample not for sale
HYLO®-GEL	Sweden	38.2594 SE 55.1114 SE	10 ml 10 ml – sample not for sale
HYLO®-FORTE	United Kingdom	38.2746 55.0298	10 ml 7.5 ml – sample not for sale
HYCOSAN EXTRA	United Kingdom	55.0162 55.0195	7.5 ml 7.5 ml – sample not for sale