

URSAPHARM Arzneimittel GmbH  
Industriestraße 35  
66129 SAARBRÜCKEN  
GERMANY

DOC\_HYLO DUAL\_EC\_2020-02

## 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.: DD 60132729 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 V 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 Is, 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 V, section 4 of the aforementioned directive. The conformity of the production full quality assurance system set out in Annex V, 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 60146387 0001**, issued on **07/02/2020** is delivered by **TÜV Rheinland LGA Product GmbH**.

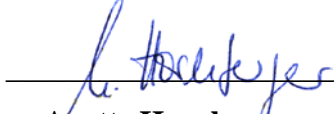
This Declaration of Conformity covers **sterile eye drops and sterile nasal preparations** as specified in the product list belonging to this declaration, and is only valid in connection with a batch-specific **Certificate of Compliance** for all products concerned bearing the CE marking and manufactured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

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Saarbrücken, February 2020

Annex: Product list

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Anette Hornberger  
Head of Regulatory Affairs

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

## PRODUCT LIST

This product list belongs to the Declaration of Conformity identified by **DOC\_HYLO-DUAL\_EC\_2020-02** 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 DUAL®	Austria	55.0890	10 ml
HYLO DUAL®	Belgium	55.0881 55.0882	10 ml 10 ml – sample not for sale
HYLO DUAL®	Czech Republic	55.0869	10 ml
HYLO-DUAL®	Denmark	55.1250 55.1251	10 ml 10 ml – sample not for sale
HYLO-DUAL®	Finland	55.1250 55.1251	10 ml 10 ml – sample not for sale
HYLO DUAL®	France	55.0957 55.0958	10 ml 10 ml – sample not for sale
HYLO DUAL®	Germany	55.0545 55.0546	10 ml 10 ml – sample not for sale
HYLO DUAL®	Greece	55.1856	10 ml
HYLO-DUAL	Ireland	55.1366 55.1367	7.5 ml 7.5 ml – sample not for sale
HYLO DUAL®	Italy	55.1695	10 ml
HYLO DUAL®	Luxemburg	55.0881 55.0882	10 ml 10 ml – sample not for sale
HYLO DUAL®	Netherlands	55.0881 55.0882	10 ml 10 ml – sample not for sale
HYLO-DUAL®	Norway	55.1250 55.1251	10 ml 10 ml – sample not for sale
HYLO DUAL®	Poland	55.0865 55.0886	10 ml 10 ml – sample not for sale
HYLO DUAL®	Portugal	55.1228 55.1229	10 ml 10 ml – sample not for sale
HYLO DUAL®	Slovak Republic	55.0869	10 ml
HYLO-DUAL®	Spain	55.0870 55.0871	10 ml 10 ml – sample not for sale
HYLO-DUAL®	Sweden	55.1250 55.1251	10 ml 10 ml – sample not for sale

Trade Name	Country	Article no. finished product	Pack size
HYLO-DUAL <sup>®</sup>	Switzerland	55.1016 55.1329	10 ml 10 ml – sample not for sale
HYLO <sup>®</sup> -DUAL	United Kingdom	55.1191 55.1406	10 ml 7.5 ml – sample not for sale
HYCOSAN <sup>®</sup> DUAL	United Kingdom	55.1364 55.1365	7.5 ml 7.5 ml – sample not for sale