URSAPHARM Arzneimittel GmbH
Industriestraße 35
66129 SAARBRÜCKEN
GERMANY

DOC_HYLO DUAL INTENSE_EU_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.: HD 60132728 0001, CE0197**, issued on **25/07/2019** 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 IIb 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 aforementioned 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 60146387 0001**, issued on **07/02/2020** is 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
66129 SAARBRÜCKEN
GERMANY

Saarbrücken, Februar 2020

Anette Hornberger
Head of Regulatory Affairs

Annex: Product list

Annex to the Declaration of Conformity - DOC_HYLO DUAL intense_EU_2020-02

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PRODUCT LIST

This product list belongs to the Declaration of Conformity identified by **DOC_HYLO DUAL intense_EU_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 INTENSE®	Austria	55.1789	10 ml
HYLO DUAL INTENSE®	Belgium	55.1790 55.1845	10 ml 10 ml – sample not for sale
HYLO DUAL INTENSE®	Czech Republic	55.1791	10 ml
HYLO DUAL INTENSE®	Denmark	55.1794 55.1844	10 ml 10 ml – sample not for sale
HYLO DUAL INTENSE®	Finland	55.1794 55.1844	10 ml 10 ml – sample not for sale
HYLO DUAL INTENSE®	Germany	55.1562 55.1563	10 ml 10 ml - sample not for sale
HYLO DUAL INTENSE®	Greece	55.1863	10 ml
HYLO DUAL INTENSE®	Luxembourg	55.1790 55.1845	10 ml 10 ml – sample not for sale
HYLO DUAL INTENSE®	Netherlands	55.1790 55.1845	10 ml 10 ml – sample not for sale
HYLO DUAL INTENSE®	Norway	55.1794 55.1844	10 ml 10 ml – sample not for sale
HYLO DUAL INTENSE®	Poland	55.1792	10 ml
HYLO DUAL INTENSE®	Slovak Republic	55.1791	10 ml
HYLO DUAL INTENSE®	Spain	55.1795	10 ml
HYLO DUAL INTENSE®	Sweden	55.1794 55.1844	10 ml 10 ml – sample not for sale
HYLO DUAL INTENSE®	Switzerland	55.1793	10 ml