

URSAPHARM Arzneimittel GmbH
Industriestraße 35
66129 SAARBRÜCKEN
GERMANY

DOC_HYLO-COMOD_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**.

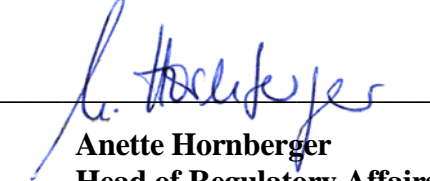
This declaration is supported by the Quality System certification based on the harmonized standards ISO 9001:2015 and EN ISO 13485:2016, Quality System Certificates with registration numbers: **01 100 1810001**, issued on **21/02/2020** and **SX 60146387 0001**, issued on **07/02/2020** are delivered 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
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Saarbrücken, April 2020

Annex: Product list



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-COMOD_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 COMOD®	Austria	55.0732 55.0734	10 ml 2 x 10 ml
HYLO COMOD®	Belgium	38.2130 BE 39.2657 BE	10 ml 2 ml – sample not for sale
Hylo-COMOD®	Cyprus	55.0285	10 ml
HYLO COMOD®	Czech Republic	38.2136 CZ 38.2845 CZ	10 ml 2 x 10 ml
HYLO-COMOD	Denmark	38.2137 DK 55.1116 DK	10 ml 10 ml – sample not for sale
Hylo-COMOD	Estonia	55.0748 EE	10 ml
HYLO-COMOD	Finland	38.2137 FI 55.1116 FI	10 ml 10 ml – sample not for sale
HYLO CONFORT®	France	55.0791 55.0805	10 ml 10 ml – sample not for sale
HYLO COMOD®	Germany	38.1958 55.0206 38.2338	10 ml 10 ml – sample not for sale 2 x 10 ml
HYLO COMOD	Greece	38.2133	10 ml
Hycosan	Ireland	38.2756 IE 55.0358	7.5 ml 7.5 ml – sample not for sale
HYLO COMOD®	Italy	55.1530	10 ml
Hylo-COMOD	Latvia	55.0748 LT	10 ml
Hylo-COMOD	Lithuania	55.0748 LV	10 ml
HYLO COMOD®	Luxemburg	38.2130 LU 39.2657 LU	10 ml 2 ml – sample not for sale
HYLO-COMOD®	Malta	38.2131	10 ml
HYLO COMOD®	Netherlands	38.2130 NL 39.2657 NL	10 ml 2 ml – sample not for sale
HYLO-COMOD®	Norway	38.2137 NO 55.1116 NO	10 ml 10 ml – sample not for sale
HYLO COMOD®	Poland	38.2151	10 ml

Trade Name	Country	Article no. finished product	Pack size
HYLO COMOD®	Portugal	55.1224 55.1225	10 ml 10 ml – sample not for sale
HYLO-COMOD®	Romania	55.1138 55.1404	10 ml 10 ml – sample not for sale
HYLO COMOD®	Slovak Republic	38.2136 SK 38.2845 SK	10 ml 2 x 10 ml
HYLO-COMOD	Spain	55.0592 55.0593	10 ml 10 ml – sample not for sale
HYLO-COMOD®	Sweden	38.2137 SE 55.1116 SE	10 ml 10 ml – sample not for sale
Hycosan	United Kingdom	38.2756 UK 55.0946 55.0358	7.5 ml 7.5 ml (Boots) 7.5 ml – sample not for sale