

URSAPHARM Arzneimittel GmbH
Industriestraße
66129 SAARBRÜCKEN
GERMANY

DOC_HYLO NIGHT_EU_2021-11

DECLARATION OF CONFORMITY

We hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by the "CE Marking of Conformity Certificate", **No. 2018308CE01**, first issued on **19/08/2002**, revised on **12/04/2016**, reissued on **29/09/2017** and delivered by **DEKRA Certification B.V. – Meander 1051 - 6825 MJ ARNHEM, THE NETHERLANDS, Notified Body Identification Number 0344**, and conform to the required technical documentation, in accordance with Annex II excluding (4) for the class IIb products of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC, concerning medical devices.

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

This declaration based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex II excluding (4) of the EC-Directive. The conformity of the production quality assurance set out in Annex II excluding (4), is described in the said CE Marking of Conformity Certificate, issued and delivered by **DEKRA Certification B.V.**

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 **18/11/2021** is delivered by **TÜV Rheinland LGA Product GmbH**.

This Declaration of Conformity covers **sterile eye care products** 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
66129 SAARBRÜCKEN
GERMANY

Saarbrücken, 25 November 2021


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 NIGHT_EU_2021-11** and specifies the CE marked products concerned that **URSAPHARM Arzneimittel GmbH** distributes in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC concerning medical devices. The following list identifies the products by **name, dosage form, country, and article-number**.

Trade Name	Dosage form	Country	Article no. finished product
VitA POS [®]	Eye ointment	Austria	55.0705 – 5 g
HYLO NIGHT [®]	Eye ointment	Austria	55.1870 – 5 g
VitA POS [®]	Eye ointment	BE/LU/NL	38.1549 – 5 g
HYLO NIGHT [®]	Eye ointment	BE/LU/NL	55.2053 – 5 g
VitA-POS [®]	Eye ointment	Cyprus	55.0287 – 5 g
VitA POS [®]	Eye ointment	CZ/SK	55.0971 – 5 g
VitA-POS [®]	Eye ointment	DK/FI/NO/SE	38.2684 – 5 g
VitA-POS [®]	Eye ointment	EE/LT/LV	38.2640 – 5 g
VitA Nuit [®]	Eye ointment	France	55.0825 – 5 g 55.0852 – 5 g “sample not for sale”
VitA POS [®]	Eye ointment	Germany	38.1888 – 5 g 55.0212 – 5 g “sample not for sale”
HYLO NIGHT [®]	Eye ointment	Germany	55.1829 – 5 g 55.1831 – 5 g “sample not for sale”
VitA POS [®]	Eye ointment	Greece	38.1682 – 5 g
VitA-POS [®]	Eye ointment	Italy	55.0597 – 5 g 55.0598 – 5 g “sample not for sale”
HYLO [®] NIGHT	Eye ointment	Italy	55.1576 – 5 g
VitA POS [®]	Eye ointment	Malta	55.1735 – 5 g
VitA POS [®]	Eye ointment	Poland	38.1762 – 5 g 55.0884 – 5 g “sample not for sale”
HYLO NIGHT [®]	Eye ointment	Poland	55.1970 55.1971 – 5 g “sample not for sale”
VitA-POS [®]	Eye ointment	Portugal	55.1234 - 5 g 55.1235 - 5 g “sample not for sale”
HYLO NIGHT [®]	Eye ointment	Portugal	55.1698 - 5 g
VitA POS [®]	Eye ointment	Romania	55.1141 - 5 g
VitA POS [®]	Eye ointment	Spain	55.0647 - 5 g 55.0648 - 5 g “sample not for sale”
VitA POS [®]	Eye ointment	Switzerland	38.1930 - 5 g
HYLO NIGHT [®]	Eye ointment	Switzerland	55.1931 - 5 g
VitA-POS [®]	Eye ointment	United Kingdom	55.0167 - 5 g 55.0260 - 5 g “sample not for sale”

Trade Name	Dosage form	Country	Article no. finished product
Hycosan [®] NIGHT	Eye ointment	United Kingdom	55.1421 - 5 g 55.2052 - 5 g “sample not for sale”
HYLO NIGHT [®]	Eye ointment	United Kingdom	55.1761 - 5 g 55.1762 - 5 g “sample not for sale”