

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60151577 0001

**Report No.:** 3334396 030

**Manufacturer:** URSAPHARM Arzneimittel GmbH  
Industriestr. 35  
66129 Saarbrücken  
Deutschland

**Products:** Sterile eye drops and sterile nasal preparations  
(see attachment for products included)  
Replaces Approval, Registration No.: DD 60132729 0001

**Expiry Date:** 2024-02-06

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2020-11-05

**Date:** 2020-11-05

Notified Body

  
Dr. K. Kluge



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** DD 60151577 0001  
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**Manufacturer:** URSAPHARM Arzneimittel GmbH  
Industriestr. 35  
66129 Saarbrücken  
Deutschland

**Products of class IIa:**

- Carbomer containing Eye gel:  
Lakripos Gel

**Date:** 2020-11-05

**Notified Body**

*Dr. K. Kluge*  
**Dr. K. Kluge**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

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For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions (class I, sterile)

- Isotonic salt solution (nasal spray/nasal drop):  
Ocean Spray, Ocean Sea Water Nasal Spray
- Sodium hyaluronate containing nasal spray/nasal drops:  
hysan nasal spray, hysan hyaluronate spray  
hysan hyaluronate drops, HYSAN-BABY
- Sodium hyaluronate and dexpanthenol containing nasal spray:  
hysan care spray
- Hypertonic sea water nasal spray:  
hysan Salinspray

**Date:** 2020-11-05

**Notified Body**

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For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions (class I, sterile)

- Hypromellose containing eye drops:  
Tear-Lac
- Sodium hyaluronate containing and Enphrasia off.-  
containing eye drops:  
HYLO FRESH  
Hycosan Fresh
- Sodium hyaluronate containing and ectoin containing  
eye drops:  
HYLO DUAL  
HYCOSAN DUAL
- Povidone containing eye drops:  
WET-COMOD

**Date:** 2020-11-05

**Notified Body**

*Dr. K. Kluge*  
**Dr. K. Kluge**

