

OPHTHALMO Pro GmbH  
Im Reihersbruch 1  
66386 Sankt Ingbert

## Field safety notice (FSN)

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### **Recall**

regarding

**Optyluron NHS 1.0% and 1.4%**

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19.05.2022

**Sender:**

Ophthalmopro GmbH  
Im Reihersbruch 1  
66386 Sankt Ingbert  
SRN: DE-MF-000020319

**Addressee:**

All distributors and users of the product

**Identification of affected medical devices:**

Optyluron NHS 1.0% and 1.4% in sizes 0.55 ml 0.85 ml

All products that are still within expiry date must be recalled.

**Description of the problem including the identified cause:**

The sterility of the products cannot be guaranteed. For this reason, all products must be recalled immediately.

**What measures are to be taken by the addressee?**

Please confirm receipt of the Field Safety Notice immediately and let us know how many products you still have in stock so that we can arrange for collection of the goods. For this purpose, please fill out Attachment 1 and send it by e-mail to [office@ophthalmo-pro.de](mailto:office@ophthalmo-pro.de) or by fax to 0 68 94 99 88 77 7.

The products can not be used anymore.

**Disclosure of the information described herein:**

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this **Field Safety Notice**. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.

Please keep this information at least until the action has been completed.

The "Bundesinstitut für Arzneimittel und Medizinprodukte" (BfArM) has received a copy of this "Field Safety Notice".

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### **Contact:**

Thomas Zimmer  
CEO  
Tel: +49 6694 9988770  
[office@ophthalmo-pro.de](mailto:office@ophthalmo-pro.de)

Frank Tillmann  
SBMPG / PRRC  
Tel: +49 171 4218130  
[vp@ftillmann.de](mailto:vp@ftillmann.de)

We apologize for the inconvenience.

Thomas Zimmer, CEO

Frank Tillmann, SBMPG/PRRC

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Attachment 1:

19.05.2022

**Please send us this form filled out by**

**Fax to 0 68 94 99 88 77 7**

**Mail to [office@ophthalmo-pro.de](mailto:office@ophthalmo-pro.de)**

☐ No, we have no more goods in stock.

☐ Yes, we still have goods in stock. (Please enter your stock levels below).

Optyluron NHS 1.0% 0.55ml \_\_\_\_\_

Optyluron NHS 1.0% 0.85ml \_\_\_\_\_

Optyluron NHS 1.4% 0.85ml \_\_\_\_\_

Optyluron NHS 1.4% 0.55ml \_\_\_\_\_

Ready for collection from (Date): \_\_\_\_\_

Collection address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Contact: \_\_\_\_\_

Phone number: \_\_\_\_\_