



Aivimed GmbH  
Borsigstr. 34  
65205 Wiesbaden

## Field safety notice (FSN)

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### **Recall**

regarding

***AVISC 1% 0,55 ml und 0,85 ml***  
***AVISC phaco 2,5% 0,55 ml und 0,85 ml***  
***AVISC bio 1,5% 0,55 ml und 0,85 ml***  
***AVISC plus 1,4% 0,55 ml und 0,85 ml***

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19.05.2022

#### **Sender:**

Aivimed GmbH  
Borsigstr. 34  
65205 Wiesbaden

#### **Addressee:**

All distributors and users of the product

#### **Identification of affected medical devices:**

AVISC 1% 0,55 ml und 0,85 ml  
AVISC phaco 2,5% 0,55 ml und 0,85 ml  
AVISC bio 1,5% 0,55 ml und 0,85 ml  
AVISC plus 1,4% 0,55 ml und 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 [info@aivimed.com](mailto:info@aivimed.com) or by fax to + 49 (0) 611 450 3220.

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



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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".

### **Contact:**

Jürgen Schröder  
CEO  
Tel: +49 0611 450320  
[info@aivimed.com](mailto:info@aivimed.com)

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

We apologize for the inconvenience.

Jürgen Schröder, CEO

Frank Tillmann, SBMPG/PRRC

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A handwritten signature in black ink, appearing to read 'F. Tillmann', positioned above a horizontal line.



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Attachment 1:

**Please send us this form filled out by**  
**Fax to + 49 (0) 611 450320**  
**Mail to [info@aivimed.com](mailto:info@aivimed.com)**

- No, we have no more goods in stock.  
 Yes, we still have goods in stock. (Please enter your stock levels below).

AVISC 1% 0,55 ml

AVISC 1% 0,85 ml

AVISC phaco 2,5% 0,55 ml

AVISC phaco 2,5% 0,85 ml

AVISC bio 1,5% 0,55 ml

AVISC bio 1,5% 0,85 ml

AVISC plus 1,4% 0,55 ml

AVISC plus 1,4% 0,85 ml

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

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



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

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