

Wöhlk Contactlinsen GmbH
Safety Officer Mirko Tamm
Bürgermeister-Schade-Straße 12
24232 Schönkirchen

Schönkirchen, on 14/01/2020

URGENT SAFETY INFORMATION

VOLUNTARY RECALL

Voluntary Recall of a Batch of the *CONTACT AIR spheric* Contact Lenses of Wöhlk Contactlinsen GmbH

Dear customer,

Wöhlk Contactlinsen GmbH is recalling a batch of the ***CONTACT AIR spheric*** contact lenses. This recall concerns the batch specified below exclusively and not any other batches!

Trade name:	<i>CONTACT AIR spheric</i>
Packaging unit:	6-pack
Product specifications:	Base curve: BC 8.50; strength: -2.25 dpt; diameter: 14.20
Batch, lot no.:	LOT 20390605400
Date of manufacture:	08-2019
Best-before date:	08-2021

1. Problem description

We are making this voluntary product recall to ensure that our products can be used safely. We were notified of an incident where a ***CONTACT AIR spheric*** contact lens caused an unpleasant burning sensation in the eye when inserted for the first time directly after having been taken out of the blister packaging, requiring medical care. No serious adverse health effects were caused according to the medical assessment.

Unfortunately, our cause analysis process cannot rule out completely the possibility that the storage solution was faulty and filled into the blister packaging in the manufacturing process of the contact lens. This fault only relates to the batch with lot number 20390605400.

Since our customers' health is our highest priority, and to ensure that no similar incidents will occur with the contact lens, we are voluntarily recalling the relevant batch, asking you for your support.

2. Health risk

A **CONTACT AIR spheric** contact lens of the relevant batch may cause a burning sensation in and reddening of the eye when being used.

3. Measures to be taken by the customer

1. Please check your inventory list for the relevant batch. You can find the LOT number both on the primary packaging (blister) and on the folding box, see photo:



2. Stop the use and remove the identified contact lenses from your inventory. Please send all of these contact lenses to us. You will receive a replacement or a credit note from us.
3. Any other products of Wöhlk Contactlinsen GmbH are not affected and may continue to be used.
4. Please fill out the enclosed Confirmation & Return Form and send it to the specified address. If you no longer have any stock, please send the form back in this case as well so that the public authorities can be notified accordingly.

This notification should be forwarded to affected customers, to all persons in your organisation who need to be informed thereof and to all organisations to whom these potentially affected products had been redirected.

The competent supervisory authorities will be notified of this measure.

Both the safe and reliable use of our products and our customers' well-being and satisfaction are of particular importance to us. We are aware of the inconveniences caused to you by this measure and thank you for supporting us by returning this product to us!

Yours sincerely

Mirko Tamm
Grad. Eng. (UoAS) Ophthalmic Optics
Medical Devices Safety Officer
Head of Professional Services

Enclosure(s)

Confirmation Form

Confirmation Form

VOLUNTARY PRODUCT RECALL - letter dated 14/01/2020

According to our documents, you have received the affected product.

Please fill out the form in full and send it back **as soon as possible** to:

fax number: +49 (0) 431 991-110 or

by e-mail: mirko.tamm@woehlk.com

Trade name: *CONTACT AIR spheric*
Packaging unit: 6-pack
Product specifications: Base curve: BC 8.50; strength: -2.25 dpt; diameter: 14.20
Batch, lot no.: LOT 20390605400
Date of manufacture: 08-2019
Best-before date: 08-2021

To be completed by the customer:

<input type="checkbox"/> *	Number of products of this batch that had been sold to end consumers:	Number:
<input type="checkbox"/> *	Contact lenses of this batch that had already been sent back to Wöhlk Contactlinsen.	Number:
<input type="checkbox"/> *	We will send the affected products back to: Wöhlk Contactlinsen GmbH Safety Officer Mirko Tamm Bürgermeister-Schade-Straße 12-16 24232 Schönkirchen	
	Lot number: 20390605400	Number:

*: Please tick all appropriate boxes

I have received and taken note of the urgent safety information of Wöhlk Contactlinsen GmbH relating to the product recall of the **CONTACT AIR spheric** contact lens.

The person filling out the form confirms receipt and takes note of the measure described in the letter on the product recall.

Company:

Address:

Point of contact:

Department:

Place, date

Name, signature

Wöhlk-internal

Date of receipt of the response:

Name, signature