6201 South Freeway
Fort Worth, Texas 76134-2099
www.alcon.com

URGENT: VOLUNTARY FIELD SAFETY CORRECTIVE ACTION	
Description	Specific lots of DAILIES TOTAL1® and TOTAL 30® contact lenses
Product Reference	DAILIES TOTAL1® ,TOTAL 30®

August 12, 2024

SPLENDOR d.o.o

Dear Valued Customer,

Alcon has initiated a Voluntary Field Safety Corrective Action for specific lots of DAILIES TOTAL1® and TOTAL 30® contact lenses. We identified an isolated quality issue with a material supplied by a third-party vendor that was used in the production of these specific contact lens lots at a single manufacturing site. As a result, the identified contact lens lots may not meet Alcon quality and/or performance standards for the entirety of their labeled shelf life.

The contact lenses from the identified lots are not expected to cause an increased risk to the wearer. As with any contact lens, there is a remote likelihood that wearing a lens from the identified lots may lead to temporary issues such as irritation, redness, or blurred vision. These symptoms typically resolve after lens removal and/or replacement (as directed in the patient leaflet).

We ask that you stop any further distribution of contact lenses from the identified lots and request that you contact any eye care practitioners, patients, or others to whom you have distributed the identified lots.

Alcon is committed to delivering outstanding product quality and customer service, and we regret the inconvenience caused by this action.

Sincerely,

Sanja Banek Babic Banek Babic, Sanja Digitally signed by Banek Babic, Sanja DN: cn=Banek Babic, Sanja, ou=PDF Internal Signing, o=Alcon Vision, LLC Date: 2024.08.13 09:38:28 +02'00'

Regulatory affairs associate director CSEEC

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According to our records, the following contact lens lots have been shipped to your firm and are affected by this Field Safety Corrective Action :

Table 1: Affected contact lens lots shipped to your firm

Description	Batch	Quantity	Delivery
DAILIES TOTAL 1 30P 850 141 -03.75	N1275792	2	1615526895
DAILIES TOTAL 1 30P 850 141 -01.75	N1275793	1	1615307791
DAILIES TOTAL 1 30P 850 141 -01.50	N1275802	3	1615526895
DAILIES TOTAL 1 30P 850 141 -01.50	N1276271	1	1615307791
TOTAL30 SPHERE 3P 840 142 -05.50	N4160927	6	1614757847

Actions to take

Alcon asks that you stop distribution of the identified lots of DAILIES TOTAL1® and TOTAL 30® and dispose of any remaining product from the identified lots which may remain in your inventory.

To execute this medical device action, please take the following steps:

1. Stop any further distribution of product from the identified lots.
2. Review your inventory to determine if you have any product from the identified lots within your facility. See **Table 1** for affected DAILIES TOTAL1® and TOTAL 30® lots that have been shipped to your firm.
3. Dispose of any product from the identified lots which remains at your facility. If immediate disposal is not feasible, ensure the identified lots are segregated from other products until disposal can be completed.
4. Fill out the attached 'Response Form', **even if you have zero (0) units remaining in inventory** and return the form to Alcon using the contact information provided on the form.
5. Forward this notification to others within your organization who may be in possession of product from the identified lots.
6. Contact other organizations, eye care providers and/or individuals, whenever this is feasible, to whom you have transferred or distributed the identified lots to advise them of this Voluntary Medical Device Field Safety Corrective Action and request they dispose of contact lenses from the identified lots. For your convenience, a Voluntary

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Medical Device Field Safety Corrective Action notification template is attached for your use in communicating this issue to your customers.

For further assistance

Topic	Contact
Questions regarding this Voluntary Medical Device Action including inquiries regarding stock replacement or account credits	Your Alcon account manager or Customer Service
Report an adverse event or product quality issue to Alcon	qa.complaints@alcon.com

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RESPONSE FORM

Alcon DAILIES TOTAL1® and TOTAL 30®

Splendor d.o.o.

MA# 2024.016

To execute this medical device Field Safety Corrective Action, please take the following steps:

1. Stop any further distribution of product from the identified lots.
2. Review your inventory to determine if you have any product from the identified lots within your facility. See **the table below** for a list of affected DAILIES TOTAL1® lots that have been shipped to your firm.
3. Dispose of any product from the identified lots which remains at your facility. If immediate disposal is not feasible, ensure the identified lots are segregated from other products until disposal can be completed.
4. Fill out this 'Response Form', including the number of packs discarded for each batch, **even if you have zero (0) units remaining in inventory** and return the form to Alcon using the contact information provided below.
5. Forward this notification to others within your organization who may be in possession of product from the identified lots.
6. Contact other organizations, eye care providers and/or individuals to whom you have transferred or distributed the identified lots to advise them of this Voluntary Medical Device Field Safety Corrective Action and request they dispose of contact lenses from the identified lots.

Product description	**Affected lot(s)**	**Number packs discarded** (please complete)
« Material_description »	« Batch_number »	

Return this response form via **email to sanja.banek-babic@alcon.com**

Your signature below attests that you have read and understood this notice, and that you agree to complete the actions specified herein.

Signature:	**Date:**
Printed Name:	
Title:	