Rev 1: September 2018
FSN Ref: 0020-1790 FSCA Ref: 0020-1791

Date: 06Mar2021

Urgent Field Safety Notice
Extreme H2O 59% Daily Contact Lenses

For Attention of*:Logistics Manager or Site Manager

Contact details of local representative (name, e-mail, telephone, address etc.)*

Distributor	Address	City	Zip	Country	Phone
Techlens WL Contactlinsen Gmbh	Schleissheimer Str 267	Munchen	80809	Germany	49893236700
Hydrolens - Vision Care	Nordlandsvej 86	Risskov	8240	Denmark	4586271766
Galifa Contactlinsen	Zurcherstrasse 204e	Saint Gallen	9014	Switzerland	41712723000
Ercon Bv	Afrikaweg 51	Assen	9407	The Netherlands	31592405000

Please also feel free to contact Clerio Vision at +1-941-739-1382 between 9am and 5pm EST or email us at sarasotacustomercare@cleriovision.com.

Rev 1: September 2018

FSN Ref: 0020-1790 FSCA Ref: 0020-1791

Urgent Field Safety Notice (FSN)
Extreme H2O 59% Daily Contact Lenses
Mislabelled Product

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Sterile soft contact lens
1.	2. Commercial name(s)
	Extreme H2O 59% Daily Lens
1.	3. Primary clinical purpose of device(s)*
	Spherical soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity.
1.	4. Device Model/Catalogue/part number(s)*

UPC Code	Product	Power	Package
675506700657	Extreme H2O 59 Xtra	+3.75	6 Pack
675506668650	Extreme H2O 59 Xtra	+3.75	Individual

1.	5. Affected serial or lot number range
	Lot: 0114511565

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	It has been determined that Lot#:0114511565 had lenses that were accidentally mis-labelled. The power of the lens printed on the label shows +3.75 Diopters when in fact, some of the lens in the blister packages are a -2.00 Diopter lens.
2.	2. Hazard giving rise to the FSCA*
	The only existing hazard is reduced visual acuity. Given that 5.75 diopter difference this issue would be immediately noticed by the patient and they would remove and not use the lens due to the lack of visual acuity. These lenses have been sterilized and are safe for use. They will only reduce visual acuity.
2.	3. Probability of problem arising
	50%
2.	4. Predicted risk to patient/users
	No harm exists for the patient. Only a noticeable loss in visual acuity
2.	5. Background on Issue
	This issue was discovered by customer complaint. The root cause has been determined and all existing inventory segregated. Additional quality checks will be added to the process to prevent future occurrences.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☒ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Not critical to safety but should be returned or destroyed with evidence of destruction returned to Clerio Vision as soon as possible.
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None All affected product is being removed from the market and additional quality checks are being put in place to avoid future occurrence	
3	5. By when should the action be completed?	Not critical to safety but should be returned or destroyed with evidence of destruction returned to Clerio Vision as soon as possible.
3.	6. Is the FSN required to be communicated to the patient /lay user?	Yes
3	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Yes Appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Clerio Vision
	b. Address	7575 Commerce Ct. SARASOTA, FL 34243 USA
	c. Website address	https://extremeh2o.com/
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes	
4.	5. List of attachments/appendices:	Customer Response
4.	6. Name/Signature	**Ian Kelsey** **Quality Manager**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	0020-1790
FSN Date*	Pre-filled by manufacturer
Product/ Device name*	Extreme H20 59 Xtra
Product Code(s)	675506700657, and 675506668650
Batch/Serial Number (s)	Lot Number 0114511565

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
☐	Other Action (Define):			

☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	sarasotacustomercare@cleriovision.com
Customer Helpline	+1-941-739-1382 between 9am and 5pm EST
Postal Address	7575 Commerce Ct. SARASOTA, FL 34243 USA
Web Portal	https://extremeh2o.com/
Fax	+1-941-758-6887 ATTN: Customer Service
Deadline for returning the customer reply form*	30 Apr 2021

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.