

Rev 1: September 2018

FSN Ref: FSN Danmark BIO Lens

FSCA Ref: CAPA24010 FSCA

Dat: 15 April 2024

**Urgent Field Safety Notice**  
**Bio Lens Daily and Bio Lens Month**

**For Attention of\*:** Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

<b>Contact details of local representative (name, e-mail, telephone, address etc.)*</b>
Vision Care APS, Nordlandsvej 86, 8240 Risskov, Danmark. Contact person: Peter Honoré Vestergaard, phv@visioncare.dk This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

**Urgent Field Safety Notice (FSN)**  
**Bio Lens Daily and Bio Lens Month**  
**Risk addressed by FSN**


<b>1. Information on Affected Devices*</b>	
1	<b>1. Device Type(s)*</b>
.	LENS (D) BIOCOMPATIBLE and LENS (M) BIOCOMPATIBLE
1	<b>2. Commercial name(s)</b>
.	Lens BIO Dag and Lens BIO Maand
1	<b>3. Primary clinical purpose of device(s)*</b>
.	The biocompatible contact lenses for daily or monthly wear are used for vision correction.
1	<b>4. Device Model/Catalogue/part number(s)*</b>
.	See attached list for model numbers.

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	<b>1. Description of the product problem*</b>
.	For contact lenses distributed in Denmark, the labelling is not in accordance with the language requirements of MDD Article 4 lid 4. The labelling does not include the Danish language.
2	<b>2. Hazard giving rise to the FSCA*</b>
.	The additional warning on the package 'Do not use if blister is damaged or seal is broken' is available in English, French, Italian, Spanish and German, in combination with the internationally harmonized symbol for 'product sterilized using steam or dry heat'. Which provides already an indication for the user to use care when using this sterile product. The severity of the risk when using the contact lens after the seal is broken is defined as an Eye infection after the use of contact lenses. User gets infected eye(s) due to use of the product
2	<b>3. Probability of problem arising</b>
.	Contact lenses are distributed through contact lens care specialists or eye doctors to the final users and upon initial use the final user receives the instructions in the applicable language by the distributor. Applying contact lenses is a common practice within the society and together with the instructions given by the professionals during initial purchase

	and continuous support during the further use of the professional the risk of wrong appliance resulting in risk for the user is determined to be acceptable. The probability for an eye infection due to the missing labelling is expected to be limited.
2	<b>4. Predicted risk to patient/users</b> In worst case situation the infection can only be resolved when health care professional provides treatment (e.g. by medical intervention). In most cases when the seal is broken, the storage fluid will evaporate and the contact lens will dry out, and cannot be used anymore. In the rare case the storage fluid is contaminated due to a broken seal and is not evaporated, the level of contamination can results in the worst case infection scenario. Since treatment is still an proper action it is deemed sufficient to retrieve products from the distributors and not to take action towards the end users.
2	<b>5. Further information to help characterise the problem</b> NA
2	<b>6. Background on Issue</b> Barnaux Healthcare is made aware of the missing labelling by their notified body Dekra 0344. No incidents are reported to the manufacturer in the past five years for the contact lenses placed on market that could be related to the missing labelling information.
2	<b>7. Other information relevant to FSCA</b> NA

<b>3. Type of Action to mitigate the risk*</b>	
<b>3.</b>	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input checked="" type="checkbox"/> Identify Device                        <input checked="" type="checkbox"/> Quarantine Device                        <input checked="" type="checkbox"/> Return Device                        <input type="checkbox"/> Destroy Device  <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input type="checkbox"/> Other                      <input type="checkbox"/> None                 </p> <p>Please report the following per mail, <a href="mailto:frontoffice@ote.nl">frontoffice@ote.nl</a>;</p> <ol style="list-style-type: none"> <li>1. Do you have any stock of the contact lenses LENS (D) BIOCOMPATIBLE and LENS (M) BIOCOMPATIBLE yes/no, see list of applicable model number attached.</li> <li>2. If yes, please inform us about the amount, model number and batch numbers</li> <li>3. Please return the product for relabelling. Transport and pick up details will be communicated by Frontoffice.</li> </ol>
<b>3.</b>	<p><b>2. By when should the action be completed?</b></p> <p style="text-align: right;">22 April 2024</p>
<b>3.</b>	<p><b>3. Is customer Reply Required? *</b> (If yes, form attached specifying deadline for return)</p> <p style="text-align: right;">Yes</p>
<b>4.</b>	

3.	<b>5. Action Being Taken by the Manufacturer</b>	
	<input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None	
The stock returned from concerning this FSN from the distributors shall be relabelled and returned to the distributor.		
3	6. By when should the action be completed?	30 April 2024
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

<b>4. General Information*</b>	
4.	1. FSN Type*                      New
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name <b>Barnaux Healthcare BV</b>
	b. Address <b>Vluchtoord 38</b>
	c. Website address                      Only necessary if not evident on letter-head.
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	4. List of attachments/appendices: <b>List of applicable model numbers</b>
4.	5. Name/Signature <b>Rob Oorthuizen</b>
	

<b>Transmission of this Field Safety Notice</b>	
<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>	

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

## Annex I List of applicable lot numbers

<b>Model nr.</b>	<b>Description</b>
<b>Daily Wear</b>	
BD+050	LENS (D) BIOCOMPATIBLE +0.50
BD+075	LENS (D) BIOCOMPATIBLE +0.75
BD+100	LENS (D) BIOCOMPATIBLE +1.00
BD+125	LENS (D) BIOCOMPATIBLE +1.25
BD+150	LENS (D) BIOCOMPATIBLE +1.50
BD+175	LENS (D) BIOCOMPATIBLE +1.75
BD+200	LENS (D) BIOCOMPATIBLE +2.00
BD+225	LENS (D) BIOCOMPATIBLE +2.25
BD+250	LENS (D) BIOCOMPATIBLE +2.50
BD+275	LENS (D) BIOCOMPATIBLE +2.75
BD+300	LENS (D) BIOCOMPATIBLE +3.00
BD+325	LENS (D) BIOCOMPATIBLE +3.25
BD+350	LENS (D) BIOCOMPATIBLE +3.50
BD+375	LENS (D) BIOCOMPATIBLE +3.75
BD+400	LENS (D) BIOCOMPATIBLE +4.00
BD-050	LENS (D) BIOCOMPATIBLE -0.50
BD-075	LENS (D) BIOCOMPATIBLE -0.75
BD-100	LENS (D) BIOCOMPATIBLE -1.00
BD-125	LENS (D) BIOCOMPATIBLE -1.25
BD-150	LENS (D) BIOCOMPATIBLE -1.50
BD-175	LENS (D) BIOCOMPATIBLE -1.75
BD-200	LENS (D) BIOCOMPATIBLE -2.00
BD-225	LENS (D) BIOCOMPATIBLE -2.25
BD-250	LENS (D) BIOCOMPATIBLE -2.50
BD-275	LENS (D) BIOCOMPATIBLE -2.75
BD-300	LENS (D) BIOCOMPATIBLE -3.00
BD-325	LENS (D) BIOCOMPATIBLE -3.25
BD-350	LENS (D) BIOCOMPATIBLE -3.50
BD-375	LENS (D) BIOCOMPATIBLE -3.75
BD-400	LENS (D) BIOCOMPATIBLE -4.00
BD-425	LENS (D) BIOCOMPATIBLE -4.25
BD-450	LENS (D) BIOCOMPATIBLE -4.50
BD-475	LENS (D) BIOCOMPATIBLE -4.75
BD-500	LENS (D) BIOCOMPATIBLE -5.00
BD-525	LENS (D) BIOCOMPATIBLE -5.25
BD-550	LENS (D) BIOCOMPATIBLE -5.50
BD-575	LENS (D) BIOCOMPATIBLE -5.75
BD-600	LENS (D) BIOCOMPATIBLE -6.00
BD-650	LENS (D) BIOCOMPATIBLE -6.50
BD-700	LENS (D) BIOCOMPATIBLE -7.00
BD-750	LENS (D) BIOCOMPATIBLE -7.50
BD-800	LENS (D) BIOCOMPATIBLE -8.00
<b>Monthly wear</b>	
BIO+025	LENS (M) BIOCOMPATIBLE +0.25
BIO+050	LENS (M) BIOCOMPATIBLE +0.50
BIO+075	LENS (M) BIOCOMPATIBLE +0.75
BIO+100	LENS (M) BIOCOMPATIBLE +1.00
BIO+125	LENS (M) BIOCOMPATIBLE +1.25

<b>Model nr.</b>	<b>Description</b>
BIO+150	LENS (M) BIOCOMPATIBLE +1.50
BIO+175	LENS (M) BIOCOMPATIBLE +1.75
BIO+200	LENS (M) BIOCOMPATIBLE +2.00
BIO+225	LENS (M) BIOCOMPATIBLE +2.25
BIO+250	LENS (M) BIOCOMPATIBLE +2.50
BIO+275	LENS (M) BIOCOMPATIBLE +2.75
BIO+300	LENS (M) BIOCOMPATIBLE +3.00
BIO+325	LENS (M) BIOCOMPATIBLE +3.25
BIO+350	LENS (M) BIOCOMPATIBLE +3.50
BIO+375	LENS (M) BIOCOMPATIBLE +3.75
BIO+400	LENS (M) BIOCOMPATIBLE +4.00
BIO+450	LENS (M) BIOCOMPATIBLE +4.50
BIO+500	LENS (M) BIOCOMPATIBLE +5.00
BIO+550	LENS (M) BIOCOMPATIBLE +5.50
BIO+600	LENS (M) BIOCOMPATIBLE +6.00
BIO-050	LENS (M) BIOCOMPATIBLE -050
BIO-075	LENS (M) BIOCOMPATIBLE -0.75
BIO-100	LENS (M) BIOCOMPATIBLE -1.00
BIO-125	LENS (M) BIOCOMPATIBLE -1.25
BIO-150	LENS (M) BIOCOMPATIBLE -1.50
BIO-175	LENS (M) BIOCOMPATIBLE -1.75
BIO-200	LENS (M) BIOCOMPATIBLE -2.00
BIO-225	LENS (M) BIOCOMPATIBLE -2.25
BIO-250	LENS (M) BIOCOMPATIBLE -2.50
BIO-275	LENS (M) BIOCOMPATIBLE -2.75
BIO-300	LENS (M) BIOCOMPATIBLE -3.00
BIO-325	LENS (M) BIOCOMPATIBLE -3.25
BIO-350	LENS (M) BIOCOMPATIBLE -3.50
BIO-375	LENS (M) BIOCOMPATIBLE -3.75
BIO-400	LENS (M) BIOCOMPATIBLE -4.00
BIO-425	LENS (M) BIOCOMPATIBLE -4.25
BIO-450	LENS (M) BIOCOMPATIBLE -4.50
BIO-475	LENS (M) BIOCOMPATIBLE -4.75
BIO-500	LENS (M) BIOCOMPATIBLE -5.00
BIO-525	LENS (M) BIOCOMPATIBLE -5.25
BIO-550	LENS (M) BIOCOMPATIBLE -5.50
BIO-575	LENS (M) BIOCOMPATIBLE -5.75
BIO-600	LENS (M) BIOCOMPATIBLE -6.00
BIO-650	LENS (M) BIOCOMPATIBLE -6.50
BIO-700	LENS (M) BIOCOMPATIBLE -7.00
BIO-750	LENS (M) BIOCOMPATIBLE -7.50
BIO-800	LENS (M) BIOCOMPATIBLE -8.00
BIO-850	LENS (M) BIOCOMPATIBLE -8.50
BIO-900	LENS (M) BIOCOMPATIBLE -9.00
BIO-950	LENS (M) BIOCOMPATIBLE -9.50
BIO-T1000	LENS (M) BIOCOMPATIBLE -10.00
BIO-T1050	LENS (M) BIOCOMPATIBLE -10.50
BIO-T1200	LENS (M) BIOCOMPATIBLE -12.00

<End of list>