4CARE GmbH \cdot Fraunhoferstraße 17 \cdot 24118 Kiel

Kiel, 11.11.2013

"Recall" of Lenscare SH-System-Monatslinsen

Dear

In the last couple of months you bought Lenscare SH-System Monatslinsen (monthly lenses) from us (article number k18830 and k18834).

Currently we are facing more customer complaints indicating quality problems with the LOT-numbers of these lenses you bought from us. The surface of these lenses can get scratches while wearing and can break in the last resort. This can lead to foreign body sensation and to limited vision. Very seldom customers informed us from irritation from the eye or had to consult an eye doctor. Fewest of your customers from Lenscare SH-System Monatslinsen had these heavy symptoms.

We would like to ask you to stop the usage of Lenscare SH-System Monatslinsen immediately. It is incompatible with our high requirements of quality for our products that you get a not 100% perfect product.

We immediately changed production of our Lenscare SH-System Monatslinsen and can now deliver correct products and quality. Please destroy any existing Lenscare SH-System Monatslinsen. Attached to this letter you will get a fax template with which you confirm that you destroyed existing contact lenses and can order new contact lenses for free. Please dial following faxnumber: 0049 431 88 11 689. You will get your replacement lenses in perfect quality right away.

In case of questions please do not hesitate to contact us directly. You will reach us from Monday till Friday from 08:00 till16:00 dialing 0049 431 88 11 840.

Your national competent authority will get a copy of this letter.

We would like to thank you for your kind support and we are very sorry for any trouble caused.





Augenoptiker-Meisterin

Leitung Kundenbetreuung

Jährlich zert ifiziert als Medizinprodukte hersteller, nach DIN EN ISO 9001/DIN EN ISO 13485

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