Johnson & Johnson Vision Care, Inc.

7500 Centurion Parkway

Jacksonville, FL 32256

{insert local market address & legal entity)

URGENT FIELD SAFETY NOTICE

1-DAY ACUVUE® MOIST® for ASTIGMATISM Brand Contact Lenses

September XX, 2019

RE: Voluntary Product Removal/Recall of Two Full and One Partial Master Lot of 1-DAY ACUVUE® MOIST® for ASTIGMATISM Brand Contact Lenses (Master Lot Numbers 395749, 395750, and 395751)

Dear Customer:

Johnson & Johnson Vision is recalling certain product lot(s) of 1-DAY ACUVUE® MOIST® for ASTIGMATISM Brand Contact Lenses. **This Action only affects the lot numbers indicated below. No other lots are affected by this Action.**

Brand name	Product Specification Base Curve (BC), Power	Master Lot Number	30-Pack Lot Numbers
1-DAY ACUVUE® MOIST® for ASTIGMATISM	BC 8.5, -6.00D/-0.75 X 180	395749	3957490101 3957490102 3957490103 3957490104 3957490105 3957490106 3957490107 3957490108 3957490109 3957490110 3957490111 3957490112

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1-DAY ACUVUE® MOIST® for ASTIGMATISM	BC 8.5, -6.00D/-1.75 X 180	395750	3957500101 3957500102 3957500103 3957500104 3957500105 3957500106 3957500107 3957500108 3957500109 3957500110 3957500111 3957500112
1-DAY ACUVUE® MOIST® for ASTIGMATISM	BC 8.5, -3.50D/-0.75 X 180	395751	3957510101 3957510102 3957510103 3957510104 3957510105

The 1-DAY ACUVUE® MOIST® for ASTIGMATISM Brand Contact Lens lot numbers are displayed in the barcode area on the back or side of each individual unit carton. The lot number is also present on the foil of each individual blister package of the contact lens.

Johnson & Johnson Vision has voluntarily initiated this Action to ensure you receive the highest quality products. We received a limited number of reports of foreign matter on the contact lens or in the contact lens blister solution. While there has been one report of lens use that resulted in discomfort and eye redness, importantly, there have been no reports of serious adverse events.

Based on a safety review by our Medical team, the presence of these small particles is associated with low potential risk if a patient inserts an affected lens in their eye. If the particles weren't noticed before insertion in the eye, it could result in eye redness, discomfort, or corneal abrasion.

We have identified the cause, taken corrective action, and are planning to implement even stronger manufacturing and quality controls based on learnings from this event.

The relevant Competent Authorities and Notified Body have been informed of this Action.

Since you have received potentially affected product, please **take the following actions, EVEN IF YOU HAVE NO INVENTORY REMAINING** affected by this recall. Johnson & Johnson Vision requires this information for reconciliation purposes with regulatory agencies.

:

1. Review your inventory and determine if you have **1-DAY ACUVUE® MOIST® for ASTIGMATISM** lenses from the impacted lots: **Master Lot 395749** (3957490101, 3957490102, 3957490103, 3957490104, 3957490105, 3957490106, 3957490107, 3957490108, 3957490109, 3957490110, 3957490111, and 3957490112)**, Master Lot 395750** (3957500101, 3957500102, 3957500103, 3957500104, 3957500105, 3957500106, 3957500107, 3957500108, 3957500109, 3957500110, 3957500111, and 3957500112), and **Master Lot 395751** (3957510101, 3957510102, 3957510103, 3957510104, and 3957510105).
2. **STOP** using all **affected** product. You can continue to use all other lots not affected by this voluntary recall.
3. Please pass this notice on to anyone in your organization who needs to be aware of the issue and ensure they maintain awareness as necessary.
4. **Use** the enclosed XXXX label to return any affected product related to this action.
5. **Contact** Customer Service at XXXXXXXX to arrange replacement product.
6. **Complete** the enclosed Customer Reply Form and return via fax to XXXXXXXX via email to vpiweb@visus.jnj.com [insert local market customer services email]

As always, any ACUVUE® patient who has a complaint about the product is urged to stop using it and contact Johnson & Johnson Vision Customer Service, the store where the product was purchased, or their eye care professional immediately. If any user experiences persistent irritation, pain or redness, or a change in vision after removing the lens, they should contact their eye care professional immediately.

Our top priority is patient safety and we hold ourselves to high standards for product quality and customer satisfaction. We remain fully committed to serving our customers with safe and effective products. We recognize the inconvenience this causes you, sincerely apologize, and appreciate your assistance in expediting return of the affected product.

Sincerely,

Title

Johnson & Johnson Vision

Johnson & Johnson Vision

FIELD ACTION CUSTOMER REPLY FORM

Please complete and return immediately EVEN IF YOU HAVE NO STOCK via Fax: 904-443-3442 or email: vpiweb@visus.jnj.com [insert local market tel number and customer services email address]

Please place an "X" in one of the boxes below.

☐ All affected products have been used or discarded.

☐ J&J Vision Sales Representative has returned all affected product inventory on our behalf.

☐ We are returning affected product **Quantity being Returned** _____

Lot Number	Quantity to be Returned
3957490101 (30 pack)	
3957490102 (30 pack)	
3957490103 (30 pack)	
3957490104 (30 pack)	
3957490105 (30 pack)	
3957490106 (30 pack)	
3957490107 (30 pack)	
3957490108 (30 pack)	
3957490109 (30 pack)	
3957490110 (30 pack)	
3957490111 (30 pack)	
3957490112 (30 pack)	

Lot Number	Quantity to be Returned
3957500101 (30 pack)	

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3957500102 (30 pack)	
3957500103 (30 pack)	
3957500104 (30 pack)	
3957500105 (30 pack)	
3957500106 (30 pack)	
3957500107 (30 pack)	
3957500108 (30 pack)	
3957500109 (30 pack)	
3957500110 (30 pack)	
3957500111 (30 pack)	
3957500112 (30 pack)	

Lot Number	Quantity to be Returned
3957510101 (30 pack)	
3957510102 (30 pack)	
3957510103 (30 pack)	
3957510104 (30 pack)	
3957510105 (30 pack)	

Customer Name:	
Customer Acct #:	
Address:	
City, State, Postal Code:	
Country	
Telephone Number:	

Person completing this form acknowledges the receipt and understanding of the actions, as stated in the Product Recall letter:

Name: (print) _____

Title/Position _____

Signature: _____

EMA CC 190911034046369

Date: _____

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Johnson & Johnson Poland Sp. z o.o.
ul. Iłżecka 24
02-135 Warsaw, Poland

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256

URGENT FIELD SAFETY NOTICE

1-DAY ACUVUE® MOIST® for ASTIGMATISM Brand Contact Lenses

September 11, 2019

RE: Voluntary Field Action of Two Full and One Partial Master Lot of 1-DAY ACUVUE® MOIST® for ASTIGMATISM Brand Contact Lenses (Master Lot Numbers 395749, 395750, and 395751)

Dear Distributor:

Johnson & Johnson Vision Care, Inc ("Johnson & Johnson Vision") is recalling certain product lot(s) of 1-DAY ACUVUE® MOIST® for ASTIGMATISM Brand Contact Lenses. **This Action only affects the lot numbers indicated below. No other lots are affected by this Action.**

Brand name	Product Specification Base Curve (BC), Power	Master Lot Number	30-Pack Lot Numbers
1-DAY ACUVUE® MOIST® for ASTIGMATISM	BC 8.5, -6.00D/-0.75 X 180	395749	3957490101 3957490102 3957490103 3957490104 3957490105 3957490106 3957490107 3957490108 3957490109 3957490110 395749011 3957490112

1-DAY ACUVUE® MOIST® for ASTIGMATISM	BC 8.5, -6.00D/-1.75 X 180	395750	3957500101 3957500102 3957500103 3957500104 3957500105 3957500106 3957500107 3957500108 3957500109 3957500110 3957500111 3957500112
1-DAY ACUVUE® MOIST® for ASTIGMATISM	BC 8.5, -3.50D/-0.75 X 180	395751	3957510101 3957510102 3957510103 3957510104 3957510105

Johnson & Johnson Vision has voluntarily initiated this Action to ensure you receive the highest quality products. We received a limited number of reports of foreign matter on the contact lens or in the contact lens blister solution. While there has been one report of lens use that resulted in discomfort and eye redness, importantly, there have been no reports of serious adverse events. We have identified the cause, taken corrective action, and are planning to implement even stronger manufacturing and quality controls based on learnings from this event.

The National Competent Authorities:

- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (Javna agencija Republike Slovenije za zdravila in medicinske pripomočke JAZMP)
- Agency for Medicinal Products and Medical Devices of Croatia (Agencija za lijekove i medicinske proizvode HALMED)
- The Hungarian National Institute of Pharmacy and Nutrition (Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézetről OGYÉI)

and Notified Body have been informed of this Action.

ACTIONS TO TAKE:

1. Do not ship any inventory listed in the enclosed notice.

2. Complete the Customer Reply Form if any inventory listed in the enclosed notice exists at your facility. Completed forms should be e-mailed to JJVC Quality Assurance at mangelov@its.jnj.com within **3 business days of receipt of** this letter.

3. Remove from your inventory any affected product listed in the enclosed notice. Affected product should be returned to the address below:

European Vision Center
Hanworth Road
Sunbury-on-Thames
TW16 5LN, UK

4. Distribute the attached or similar Field Safety Notice (translated to local languages) to all customers in your assigned region who received the affected lenses. Note that only the lot numbers listed in the enclosed notice are affected – no other lenses are affected by this action.

5. Please ensure your customers understand the importance of completing and returning the Customer Reply Form. JJVC requires this information for reconciliation purposes with regulatory agencies. Customers should complete and return the attached Customer Reply Form EVEN IF THEY HAVE NO INVENTORY REMAINING from the affected lots.

6. Expedite the return of all affected lenses from your customers to above address.

If you have any questions regarding this Conductivity Field Safety Notice, please contact Miranda Angelovski at:

Telephone: +386 41 799 122

Email: mangelov@its.jnj.com

Our top priority is patient safety and we hold ourselves to high standards for product quality and customer satisfaction. We remain fully committed to serving our customers with safe and effective products. We recognize the inconvenience this causes you, sincerely apologize, and appreciate your assistance in expediting return of the affected product.

Sincerely,

Miranda Angelovski, Business Quality Manager EMEA

Johnson & Johnson Vision

Johnson & Johnson Vision

FIELD ACTION CUSTOMER REPLY FORM

Please complete and return immediately EVEN IF YOU HAVE NO STOCK via email: mangelov@its.jnj.com

Please place an "X" in one of the boxes below.

☐ All affected products have been used or discarded.

☐ J&J Vision Sales Representative has returned all affected product inventory on our behalf.

☐ We are returning affected product **Quantity being Returned** _____

Lot Number	Quantity to be Returned	Quantity to be Returned
3957490107 (30 pack)	1	
3957490109 (30 pack)	1	

Lot Number	Quantity Received	Quantity to be Returned
3957500112 (30 pack)	4	

Distributor Name:	OKTAL PHARMA d.o.o.
Address:	Utinjska 40
City, State, Postal Code:	100020 Zagreb
Country	Croatia
Telephone Number:	+385 1 6596 849

Person completing this form acknowledges the receipt and understanding of the actions, as stated in the Product Recall letter:

Name: (print) _____

Title/Position _____

Signature: _____

Date: _____