Rev 1: September 2018
FSN Ref: 4-EBR_BURK_2024.12.10_FSN FSCA Ref: 3_EBR_BURK_2024.12.10_FSCA

Date: 10/12/2024

Urgent Field Safety Notice
Device Commercial Name

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.

Contact details of local representative (name, e-mail, telephone, address etc.)*
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)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*

1.1. Device Type(s)*

Brief description of the device(s) in plain language, including whether supplied sterile. Consider including a photo (here or in an Annex) where this would help with identification

Non-sterile, non-invasive Class I classified gel

1.2. Commercial name(s)

Add as Appendix if necessary.

AquaUltraClear, AquaUltraBasic

1.3. Unique Device Identifier(s) (UDI-DI)

Complete when this becomes available.

Product	Model	UDI
AquaUltra Clear	UC260	5996649001278
	UC260pp	5996649001308
	UC500	5996649001339
	UC1000	5996649001360
	UCK5000	5996649001407
	UCU5000	5996649001438
AquaUltra Basic	UB260	5996649000790
	UB260pp	5996649000820
	UB500	5996649000851
	UB1000	5996649000882
	UBK5000	5996649000912
	UBU5000	5996649000943

1.4. Primary clinical purpose of device(s)*

How the device(s) is/are used in the clinical setting/intended use.

AquaUltraClear, AquaUltraBasic,Topical skin coupling gel for use in non sterile, non-invasive ultrasound scanning procedures.

1.5. Device Model/Catalogue/part number(s)*

Add as Appendix if necessary.

UB260pp, UB260, UB500, UB1000, UBU5000, UBK5000, UC260pp, UC260, UC500, UC1000, UCK5000, UCU5000

1.6. Software version

Only where relevant.

1.7. Affected serial or lot number range

Where relevant. If not known, use manufacturing/distribution/expiration date as appropriate. Add as Appendix if necessary or provide web-based look-up tool.

From LOT 2024-04 to LOT 2024-10.

1.	8. Associated devices
	Within context of the FSCA eg for IVD reagents and platforms.

	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	Where there is one. Maybe "none" if eg Field Safety Notice (FSN) is to reinforce instructions for use. There is a potential risk of microbial contamination (Burkholderia stabilis) in the affected LOT of ultrasound gel. This potential link with ultrasound gel was identified during an investigation by public health authorities and the investigation is ongoing. The affected LOT was distributed within the UK and other countries during May to August 2024.
2.	2. Hazard giving rise to the FSCA*
	Details of the greatest hazard to the patient/end user that the advice/action is intended to mitigate. Make clear whether risk is to user, patient or both. Should also try to indicate the residual risk if the FSN advice/action is taken. There is a potential risk of developing infection caused by Burkholderia stabilis if the affected ultrasound gel is used. The risk is higher in patients with cystic fibrosis, severe lung disease, severe immunocompromised and intensive care patient. We have identified a new hazard: the use of non-sterile, non-invasive gels in an invasive manner, as a substitute for sterile products.
2.	3. Probability of problem arising
	Provide an indication (from incident data or prospective modelling) of the likelihood the problem will arise. Following stricter manufacturing technology and disinfection measures, the likelihood of occurrence is minimal. We have commissioned an accredited laboratory to prepare the validation plan and the related verification plan to improve the working environment and product cleanliness.
2.	4. Predicted risk to patient/users
	From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect). It poses a risk to the aforementioned patient groups. We have identified a new hazard: the use of non-sterile, non-invasive gels in an invasive manner, as a substitute for sterile products.
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue. Processing of accredited laboratory results. Monitoring the publication by national authorities.
2.	6. Background on Issue
	Eg how the manufacturer became aware; brief details of relevant incidents; root cause if known; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc. Root cause: - The employees did not comply with the regulations

	- In some cases, cleaning and disinfection were performed with tap water instead of purified water as per the requirements. - The effectiveness of the stabilizer against the Burkholderia bacteria. Long term action: We have commissioned an accredited laboratory to prepare the validation plan and the related verification plan to improve the working environment and product safety. Update of Technical File and QMS documentation. Procurement of manufacturing equipment, searching for alternative disinfectants.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA. Supplementation of the Instructions for Use (update: risk groups and usage warnings). The label will also be updated.

	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?	Specify where critical to patient/end user safety Immediate quarantine placement, removal by 15th of February, 2025 (The manufacturer undertakes the transportation)
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes E-mail communication

3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	90 days
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	Update – 4
4.	2. For updated FSN, reference number and date of previous FSN	FSN date: 15-NOV-2024 Updated FSN date: 10-DEC_2024
4.	**3. For Updated FSN, key new information as follows:**	
	Summarise any key difference in devices affected and/or action to be taken. **We have extended the recall activity to cover the product AquaUltra Clear and AquaUltra Basic.**	
4.	4. Further advice or information already expected in follow-up FSN? *	**Following the preparation of the validation and verification protocols, the technical documentation and ISO documentation will be updated based on the new measurement results.**
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice. By 31st December, 2024.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Ultragel Medical Kft**
	b. Address	**1022 Budapest, Aranka utca 12.**
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * NNGYK - Nemzeti Népegészségügyi Központ / National Public Health Center	
4.	9. List of attachments/appendices:	**Annex 1: list of authorities; Annex 2. list of distributors; Annex 3. List of Hungarian distributors**
4.	10. Name/Signature	Insert Name and Title here and signature below

	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.

Ultragel Medical Kft.
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