Company Name/Logo

Rev 1: September 2018
FSN Ref: 3-EBR_BURK_2024.11.15._FSN FSCA Ref: 2-EBR_BURK_2024.11.15._FSCA

Date: 15/11/2024

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.

k.

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

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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 ultrasound gel.
1.	2. Commercial name(s)
	Add as Appendix if necessary. AquaUltra Clear
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.

UC260	**5996649001278**
UC260pp	**5996649001308**
UC500	**5996649001339**
UC1000	**5996649001360**
UCK5000	**5996649001407**
UCU5000	**5996649001438**

1.	4. Primary clinical purpose of device(s)*
	How the device(s) is/are used in the clinical setting/intended use. Topical skin coupling gel for use in non-invasive ultrasound scanning procedures.
1.	5. Device Model/Catalogue/part number(s)*
	Add as Appendix if necessary. UC260, UC260pp, UC500, UC10000, 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 2024-3 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*
	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 during May to August 2024.
2.	2. Hazard giving rise to the FSCA*
	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.
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.
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.
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.
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 - Disinfectant efficacy **(update:** failure to comply with the contact time of the disinfectant, improper disinfection of the subunits of the soaking equipment, disinfection performed with tap water instead of properly treated water) - Stabilizer efficacy Long-term preventative action: Strengthening of infection control, laboratory testing of raw materials, regular laboratory examination of critical equipment points, and determination of microbial contamination testing methods by an accredited laboratory.
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).

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device X 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 within 90 days (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** X Product Removal X On-site device modification/inspection ☐ Software upgrade X IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified. • Comprehensive review of the entire production process (soaking, mixing, filling) • Establishment of an infection control policy with the involvement of an external expert • Re-training of employees • Regular ad-hoc checks • Hiring a quality control staff member • Updating the regulation of product release procedures • Replacement of soaking tanks and associated network pipes, replacement of fittings and valves, procurement of new disinfectant • Review of the current microbiological testing methods, searching for alternatives.	
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?	Not required - only distributors are informed.
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 - 2
4.	2. For updated FSN, reference number and date of previous FSN	FSN date: 6 Nov 2024
4.	**3. For Updated FSN, key new information as follows:**	
	Summarise any key difference in devices affected and/or action to be taken. Enhancement of actions and measures.	
4.	4. Further advice or information already expected in follow-up FSN? *	Closure of the investigation, implementation of measures.
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, Arankai 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 disztributors Annex 3. List of Hungarian disztributors
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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