

Rev November 07 .2024.

FSN Ref: 1-_Burk_2024.10.11_FSN

FSCA Ref: 1-EBR_Burk_2024.10.11_FSCA

Date: 07.11.2024.

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.

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, 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)
.	260g: 5996649001278 260pp g :5996649001308 500 g :5996649001339 1000 g: 5996649001360 5000 gk:5996649001407 5000 g: 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.
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 2024-4 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.
	3. Probability of problem arising

2	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 - 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.

	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 within 90 days

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.
3	5. Action Being Taken by the Manufacturer ☒ Product Removal ☐ Software upgrade ☐ Other ☒ On-site device modification/inspection ☒ IFU or labelling change ☐ 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.	2. For updated FSN, reference number and date of previous FSN	FSN date: 18 October 2024
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
	Root cause analysis, action plans.	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet.
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.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Ultrigel Medical Kft.
	b. Address	1022.Budapest, Aranka u. 12.
	c. Website address	www. orvosimuszor.eu
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:	If extensive consider providing web-link instead.
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.