Rev 1: September 2018
FSN Ref: FSN-2022-005 FSCA Ref: FSN-2022-005

Date: 18:MAY:2022

Urgent Field Safety Notice
Device Commercial Name

For Attention of*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*
E.mail : mbd.vigilance@thermofisher.com Telephone: +44(0) 1256 841144 Fax: +44(0) 1256 479525

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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)*
	IVD
1.	2. Commercial name(s)
	Thermo Scientific™ MicroTest™ M4RT 3mL w/o Beads NP Swab Kit 100/pk
1.	3. Unique Device Identifier(s) (UDI-DI)
	00842558109527
1.	4. Primary clinical purpose of device(s)*
	Remel MicroTest™ M4RT® is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viral and chlamydial agents.
1.	5. Device Model/Catalogue/part number(s)*
	R12705
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	472505
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	An internal technical investigation has confirmed that Thermo Scientific™ MicroTest™ M4RT 3mL w/o Beads NP Swab Kit 100/pk R12705 Lot 472505 contained the incorrect swab component. The kit contained a standard-size flocked swab, rather than a nasopharyngeal swab. Performance of the M4RT tube is unaffected.
2.	2. Hazard giving rise to the FSCA*
	Very low.
2.	3. Probability of problem arising
	Low.
2.	4. Predicted risk to patient/users
	There should be no immediate or long-term health consequences due to this kit containing the incorrect swab. The incorrect swab is readily distinguishable from the nasopharyngeal swab. Additionally, there was no objective evidence that the performance of the transport medium is in any way affected. Therefore, the clinical risk should be considered very low to negligible.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	An internal investigation has found that R12705 Lot 472505 contained the incorrect swab component.
2.	7. Other information relevant to FSCA

	Lot. 472505 with the expiry of 30-Mar-2024

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	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No Follow-up not required since performance of M4RT tube is unaffected.	
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 ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	As soon as possible
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?	
	N/A	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
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:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Remel Inc.
	b. Address	12076 Santa Fe Trail Drive Lenexa KS 66215
	c. Website address	www.thermofisher.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Customer Response Form
4.	10. Name	…
	Signature	

	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.*