

Rev 1: September 2018
FSN Ref: FSN-2021-0005
Date: 08 June 2021

FSCA Ref: FSN-2021-0005

Urgent Field Safety Notice
Remel Microdase Disk

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

Rev 1: September 2018
FSN Ref: FSN-2021-0005

FSCA Ref: FSN-2021-0005

Urgent Field Safety Notice (FSN)
Remel Microdase Disk


1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IVD
1.	2. Commercial name(s)
	Microdase Disk
1.	3. Unique Device Identifier(s) (UDI-DI)
	00848838022746
1.	4. Primary clinical purpose of device(s)*
	Remel Microdase Disk is a reagent-impregnated disk recommended for use in qualitative procedures to aid in the differentiation of <i>Staphylococcus</i> from <i>Micrococcus</i> by the detection of the oxidase enzyme.
1.	5. Device Model/Catalogue/part number(s)*
	R21132
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Carton Lot number; 3189271 Vial Lot number; 3212717
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem*</p> <p>Microdase disk Lot. 3189271 (Vial Lot. 3212717) appearance and performance is not compliant to the IFU. The disks are spotted brown in colour and should be displayed as white/grey prior to use. If the disks are used, they are not changing to the expected purple colour to show a reaction.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>Microdase disk Lot. 3189271 (Vial Lot. 3212717) appearance and performance is not compliant to the IFU.</p>
2.	<p>3. Probability of problem arising</p> <p>High</p>
2.	<p>4. Predicted risk to patient/users</p> <p>There should be no immediate or long-term health consequences from using this product. The brown spots on the discs on receipt indicate it should not be used. There are other methods for qualitative identification of staphylococci and micrococci, so there should not be any delay in determining the identification of these species. The clinical risk should be negligible.</p>
2.	<p>5. Further information to help characterise the problem</p> <p>Customer will immediately see that the disk is not white/grey, as instructed by the IFU.</p>
2.	<p>6. Background on Issue</p> <p>Two customer complaints had been received. The complaints were confirmed as the retained sample replicated the issue.</p>
2.	<p>7. Other information relevant to FSCA</p> <p>Microdase disk Lot. 3189271 (Vial Lot. 3212717) was manufactured in 01-April-2021 with the expiry of 17-September-2021.</p>

Rev 1: September 2018

FSN Ref: FSN-2021-0005

FSCA Ref: FSN-2021-0005

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	Thermo Fisher Scientific
	b. Address	Clipper Boulevard West, Cross ways industrial estate, Dartford, Kent. DA2 6PT
	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	James Filer Vice President, Quality and Regulatory, MBD
	Signature	

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

Rev 1: September 2018
FSN Ref: FSN-2021-0005

FSCA Ref: FSN-2021-0005

Customer Reply Form

1. Field Safety Notice (FSN) information				
FSN Reference number*	FSN-2021-0005			
FSN Date*	8 June 2021			
Product/ Device name*	Thermo Scientific™ Remel™ Microdase Disk			
Product Code(s)	R21132			
Batch/Serial Number (s)	Carton Lot number; 3189271 Vial Lot number; 3212717			
2. Customer Details				
Account Number				
Organisation Name*				
Organisation Address*				
Department/Unit				
Shipping address if different to above				
Contact Name*				
Title or Function				
Telephone number*				
Email*				
3. Customer action undertaken on behalf of Healthcare Organisation				
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.			
<input type="checkbox"/>	I performed all actions requested by the FSN.			
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.			
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete or N/A	Qty: N/A	Lot/Serial Number:	Date Returned (DD/MM/YY)
		Comments:		
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY)
		Qty	Credit <input type="checkbox"/>	Replacement <input type="checkbox"/>
		Comments:		
<input type="checkbox"/>	No affected devices are available for return/ destruction			
<input type="checkbox"/>	Other Action (Define):			
<input type="checkbox"/>	I do not have any affected devices.			
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).			
Print Name*				
Signature*				
Date*				
4. Return acknowledgement to sender				
Email	MBD.vigilance@thermofisher.com			
Telephone Number & Fax	Tel : +44(0) 1256 841144 & Fax :+44(0) 1256 479525			
Deadline for returning the reply form*	6 July 2021			

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.