Rev 1: July 11, 2024
FSN Ref: FSN_FA-2024-003 FSCA Ref: FSCA_FA-2024-003

Date: 11.Jul.2024

Urgent Field Safety Notice
UMIC Colistin (UM-COL-040)

To whom it may concern

Legal Manufacturer
Bruker Daltonics GmbH & Co. KG Michael Schubert – Person Responsible for Regulatory Compliance – QM Fahrenheitstr. 4 28359 Bremen, Germany fieldactions.BDAL@bruker.com

Urgent Field Safety Notice (FSN)
UMIC Colistin (UM-COL-040)
Potential false susceptible MIC results

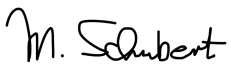
1. Information on Affected Devices*	
1.	1. Device Type(s)*
	UMIC Colistin is an in vitro diagnostic medical device for manual susceptibility testing of Enterobacterales and nonfermenting bacteria against the antibiotic colistin. 40660 - Antibacterial minimum inhibitory concentration (MIC) IVD
1.	2. Commercial name(s)
	UMIC Colistin
1.	3. Unique Device Identifier(s) (UDI-DI)
	04251204326762
1.	4. Primary clinical purpose of device(s)*
	The UMIC Colistin is an in vitro diagnostic medical device for the quantitative susceptibility testing of clinically relevant fast-growing aerobic Gram-negative bacteria (Enterobacterales, non-fermenting bacteria) against colistin using Mueller Hinton Broth, cation adjusted (CAMHB). Susceptibility is detected by determining minimum inhibitory concentration according to EUCAST or CLSI guidelines. Only pure cultures obtained from human test material can be used. The test is not automated. The device is intended for laboratory professional use only. The results of the test are intended solely as an aid to diagnosis for targeted antibacterial therapy and must not be used as single source for diagnosis, treatment or patient management decision.
1.	5. Device Model/Catalogue/part number(s)*
	UM-COL-040
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	Lot: 240410COL Lot: 240418COL Lot: 240506COL
1.	8. Associated devices
	Affected products are used in conjunction with Mueller Hinton II (UM-MH-020).

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The affected UMIC Colistin lots show an increased Colistin activity which leads to lower MIC (minimum inhibitory concentration) values and possibly false susceptible results. To our current knowledge, the results are approx. 1 (one) MIC too low.
2.	2. Hazard giving rise to the FSCA*
	The test results obtained may lead to the use of Colistin for the treatment of patients for whom Colistin is not effective. A delay of therapy may occur in cases where internal Quality Control fails prior to isolate testing.
2.	3. Probability of problem arising
	Occurrence is estimated as 3,51% of the tests currently in the field, when internal Quality Control is not performed on a regular basis

2.	4. Predicted risk to patient/users
	The results obtained may lead to the use of Colistin for the treatment of patients for whom Colistin is not effective.
2.	5. Further information to help characterise the problem
	See point 1.7 for affected LOTs
2.	6. Background on Issue
	Source: Customer complaints Affected LOTs: Internal investigation shows that other manufactured lots are not affected.
2.	7. Other information relevant to FSCA
	None

	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?	Immediately upon receipt of this FSN
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes For patients who are still undergoing Colistin treatment, the MIC (minimum inhibitory concentration) results must be checked whether they are one MIC below the breakpoint. These results may have been incorrectly interpreted as susceptible.	
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 Product has been quarantined	
3	6. By when should the action be completed?	09.Aug.2024

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?	
	Not applicable	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable
4.	**3.** For Updated FSN, key new information as follows:	
	Not applicable	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable	
4	6. Anticipated timescale for follow-up FSN	Not applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Bruker Daltonics GmbH & Co. KG
	b. Address	Fahrenheitstr. 4, 28359 Bremen, Germany
	c. Website address	www.bruker.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Acknowledgement Form
4.	10. Name/Signature	Michael Schubert, Person Responsible for Regulatory Compliance - QM 

	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.

Appendix 2 – Acknowledgement Form

To be returned to Bruker Daltonics GmbH & Co. KG
By email (PDF format): fieldactions.BDAL@bruker.com

Please, send us this form **immediately** as acknowledgement of receipt and of completion.

Acknowledgement of Receipt (AOR) – Acknowledgement of Completion (AOC)	
☐ I/we acknowledge receipt of this customer information and forward this information to all concerned users. ☐ I/we confirm that **……** (number of) packaging units of the product have been properly destroyed. ☐ Please issue us a credit note for **……** (number of) packaging units. ☐ We do not require a credit note Please contact your local support for an alternative replacement.	
Lot Number(s) and quantity of destroyed products	
Company Name	
Print Name	
Signature	
E-Mail	
Date (DD.MM.YYYY)	