DISPOSAN

Rev 1: September 2018

FSN Ref: 20210715 FSCA Ref: T 4005

Date: 21.07.2021

Urgent Field Safety Notice
Saliva Kit Disposan

For Attention of *:

Purchasers and users of Saliva kits for repetitive pool testing program for SARS-CoV-2 with PCR

Contact details of local representative (name, e-mail, telephone, address etc.)*
Disposan AG, Rütistrasse 14, CH-8952 Schlieren Disposan AG, Info@disposan.ch, 058 5233700

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Urgent Field Safety Notice (FSN)

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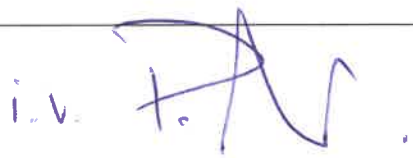
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Viral Transport Medium Tube (Saliva sample collector)
1.	2. Commercial name(s)
	Saliva Kit Disposan
1.	3. Unique Device Identifier(s) (UDI-DI)
	Na
1.	4. Primary clinical purpose of device(s)*
	Saliva sample collector for Covid 19 PCR repetitive testing
1.	5. Device Model/Catalogue/part number(s)*
	T 4005
1.	6. Software version
	Na
1.	7. Affected serial or lot number range
	2521042104; 2521042105; 2521042106; 2721042101; 2721042102; 2721042103; 2721042502
1.	8. Associated devices
	Na

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Within the scope of internal quality controls, an increased microbial load was detected in the saline solution of certain test kits. These are test kits in which the solution is already present in the test tube. Prolonged storage and elevated temperatures can lead to a proliferation of germs in the saline solution. Identification of microbes revealed several environmental and plant associated bacteria. Confirmation of these results by an independent accredited environmental laboratory is expected for mid of calendar week 29/2021. The affected test kits are mainly used for PCR saliva tests in repetitive testing in a large number of cantons. According to current knowledge, there are no indications of a risk to the health of users during the usual, prescribed application (mouth rinsing). In addition, the saline solution used has no negative influence on the quality of the test results.
2.	2. Hazard giving rise to the FSCA*
	Increased microbial load above product specifications
2.	3. Probability of problem arising
	Ten weeks after production date, an increased microbial load above product specifications has been found. Further bacterial growth is expected at temperature higher than 4 °C. Already performed analysis of common distinct human pathogens in the saline solution (i.e. E.coli, S. aureus, P. aeruginosa) exhibited a negative result in all investigated specimens.
2.	4. Predicted risk to patient/users
	As worst case severe infection with bacteria could occur to saliva kit users. According to the latest analysis results and taking into current knowledge, there are no indications of an infection risk when used as prescribed (mouth rinsing). Up to now, no feedback on illnesses has been registered.
2.	5. Further information to help characterise the problem
	Na

2.	6. Background on Issue
	The Saline Solution does not meet the expected manufacturer specifications.
2.	7. Other information relevant to FSCA
	Na

	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?	Specify where critical to patient/end user safety Return: as soon as possible, latest end of school holiday period (end of August).
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No Na	
3.	4. Is customer Reply Required? * (form attached as annex 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 Measures taken: After analysis of saline solutions, purchasers have been systematically informed on microbial load exceeding product specifications. The public is informed on the occurrence of increased microbial loads via two media releases on July 9th and July 16th 2021 widely distributed in Switzerland. Instruct purchasers to stop using and replace the affected kits. Customer reply is required. The new saline solution is supplied in a separate, sealed ampoule.	
3	6. By when should the action be completed?	End August 2021
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? Na	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Na
4.	3. For Updated FSN, key new information as follows:	
	Na	
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:	
	Na	
4	6. Anticipated timescale for follow-up FSN	Na
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Suzhou Yuno Biotechnology Co., Ltd.
	b. Address	Add:No.75 Sunwu Road, wuzhong
	c. Website address	
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes	
4.	9. List of attachments/appendices:	Customer reply
4.	10. Name/Signature	**Dr. F. Muser** **FvP Disposan** 

	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.

Annexe : Customer Reply

DISPOSAN

Disposan AG Rütistrasse 14 8952 Schlieren
058 523 37 00 www.disposan.net
CHE 110.160.479 MWST

Customer Reply Subject: Recall Saliva Kit Disposan

Dear Madam or Sir,

Please return this completed form by July 30, 2021 by mail to info@disposan.ch or fax: +41 (0) 43 322 47 09.

We have read and understood the product recall	**Yes☐ No ☐**
We have checked the stock and blocked any remaining products	**Yes☐ No ☐**
No recalled product has been shipped since 9/07/21	**Yes☐ No ☐**
We have asked the end users to return the product	**Yes☐ No ☐**

Comments:

_____

_____

Name: _____

Contact: _____

Street: _____

Zip/Place: _____

Date:_____ **Signature and stamp:**_____

Your response is mandatory.

Thank you very much for your support.

Kind regards
DISPOSAN AG