

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**

## Urgent Field Safety Notice (FSN) **Saliva Kit Disposan** Risk addressed by FSN

<b>1. Information on Affected Devices*</b>	
1	<b>1. Device Type(s)*</b>
.	Viral Transport Medium Tube (Saliva sample collector)
1	<b>2. Commercial name(s)</b>
.	Saliva Kit Disposan
1	<b>3. Unique Device Identifier(s) (UDI-DI)</b>
.	Na
1	<b>4. Primary clinical purpose of device(s)*</b>
.	Saliva sample collector for Covid 19 PCR repetitive testing
1	<b>5. Device Model/Catalogue/part number(s)*</b>
.	T 4005
1	<b>6. Software version</b>
.	Na
1	<b>7. Affected serial or lot number range</b>
.	20210324, 20210329; 2521033102; 2521040102; 2521040201; 2521040202; 2521040203; 2521040801; 2521041201; 2521041202; 2521041301; 2521041302; 2521041303; 2521041602; 2521041601; 2521041701; 2521041901; 2521042101; 2521042102; 2521042103; 2521042501; 2521051001
1	<b>8. Associated devices</b>
.	Na

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	<b>1. Description of the product problem*</b>
.	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	<b>2. Hazard giving rise to the FSCA*</b>
.	Increased microbial load above product specifications
2	<b>3. Probability of problem arising</b>
.	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	<b>4. Predicted risk to patient/users</b>
.	As worst case severe infection associated 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.



<b>4. General Information*</b>		
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	Tai zhou Sun Trine Biotechnology Co.,Ltd
	b. Address	Jianggao Road 420, 225300 Jiangsu
	c. Website address	https://en.suntrine.com/
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
		

<b>Transmission of this Field Safety Notice</b>	
	<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>

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-110.160.478 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](mailto: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:

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Name: \_\_\_\_\_

Contact: \_\_\_\_\_

Street: \_\_\_\_\_

Zip/Place: \_\_\_\_\_

Date: \_\_\_\_\_ Signature and stamp: \_\_\_\_\_

**Your response is mandatory.**

**Thank you very much for your support.**

Kind regards  
**DISPOSAN AG**

