Rev 1: December 2020
FSN Ref: OMQ2010-012-FSN-1 FSCA Ref: OMQ2010-012-FSCA

Date: 09-11-2020

Urgent Field Safety Notice
SARS-CoV-2 Rapid Antigen Test

For Attention of*:Roche Diagnostics International AG, who has distributed the products containing a swab in certain model(EZ-FINDER SWABS, IZ-01 manufactured by HuaChenYang(Shenzhen) Technology Co., Ltd.) on the UK market.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Name: RDUK Technical Support
E-mail: burgesshill.techsupportdocs@roche.com
Address: Charles Avenue, Burgess Hill, West Sussex, RH15 9RY
Mobile: UK 0808 1966822 Ireland 1800 932217

Urgent Field Safety Notice (FSN)
SARS-CoV-2 Rapid Antigen Test
Incomplete EC certification to support CE marking

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Other Virology Rapid Tests; This product is a rapid chromatographic immunoassay for the qualitative detection of specific antigens in the human nasopharynx. This product includes a sterile swab for the collection of antigens.
1.	2. Commercial name(s)
	SARS-CoV-2 Rapid Antigen Test
1.	3. Unique Device Identifier(s) (UDI-DI)
	08809319397700
1.	4. Primary clinical purpose of device(s)*
	The SARS-CoV-2 Rapid Antigen Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigen of SARS-CoV-2 present in the human nasopharynx. This test is intended to detect antigen from the SARS-CoV-2 virus in individuals suspected of COVID-19. This product is strictly intended for professional use in laboratory and Point of Care environments.
1.	5. Device Model/Catalogue/part number(s)*
	SARS-CoV-2 Rapid Antigen Test / REF: 9901-NCOV-01G / 99COV30D-EN01
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	LOT: QCO3020076 / EXP: 2022.09.06. / Quantity: 3,659 kits LOT: QCO3020077 / EXP: 2022.09.06. / Quantity: 1,417 kits LOT: QCO3020082 / EXP: 2022.09.14. / Quantity: 144 kits
1.	8. Associated devices
	Sterile swab (EZ-FINDER SWABS™, IZ-01 manufactured by HuaChenYang(Shenzhen) Technology Co., Ltd.)

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	The SARS-CoV-2 Rapid Antigen Test product from the lots affected included sterile swabs (IZ-01) manufactured by Huachenyang(Shenzhen)Technology Co., Ltd.(Made in China, EC/REP: SUNGO, UK) which has an incorrect label. The swab has not been through the correct Notified Body assessment (incomplete EC certification to support CE marking). The product is performing as specified, to our knowledge no adverse event has occurred.
2.	2. Hazard giving rise to the FSCA*
	1. Hazard: Incomplete EC certification to support CE marking The severity is 'Negligible (Level 1)' in accordance with the internal standard.
2.	3. Probability of problem arising
	1. Hazard: Incomplete EC certification to support CE marking The proportion of product sold is above 0.1 for the products that contain the conformity swaps and the nonconformity swaps. The probability is 'Frequent (Level 5)'
2.	4. Predicted risk to patient/users
	1. Hazard: Incomplete EC certification to support CE marking Risk is 5 according to the severity (Level 1, Negligible) and probability (Level 5, Frequent).

	The incomplete labelled swap has no impact on the instructions for use hence the risk for the patient can be considered as less than remote. There is no impact on the test results.
2.	5. Further information to help characterise the problem
	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 **Please forward this information to your distributors and users so that the affected products are not used.** **Information for end users:** - Please destroy the impacted lots of this product and contact your distributor. - Please check the quantity in stock and reflect the result on the form provided by the corresponding distributor. **Information for distributors:** - Please stop selling the affected product immediately, dispose of the product immediately and inform your end users. - Please check the quantity in stock and reflect the result on the form 'Attachment. Customer/Distributor Verification Form'.	
3.	2. By when should the action be completed?	2021-01-20
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No It is unlikely that the use of the incompletely labelled swab affects the diagnostic result of the IVD product.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

<table>
<tr><td>3.</td><td colspan="3">5. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☒ Other ☐ None

We will ask the distributors to stop distributing the affected products in stock. We will ask customers to stop using the affected products.</td></tr>
<tr><td>3</td><td>6. By when should the action be completed?</td><td colspan="2">2021-01-20</td></tr>
<tr><td>3.</td><td colspan="2">7. Is the FSN required to be communicated to the patient /lay user?</td><td>No</td></tr>
<tr><td rowspan="2">3</td><td colspan="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?</td></tr>
<tr><td colspan="3">NA</td></tr>
</table>

	4. General Information*	
4.	1. For updated FSN, reference number and date of previous FSN	After recognition of the incident, we have immediately investigated the affected product and issued a letter to notify Roche Diagnostics. (BA200-20201016-QA2).
4.	**2.** For Updated FSN, key new information as follows:	
	Distributors and customers advised to stop using the affected product and destroy kits	
4.	3. Further advice or information already expected in follow-up FSN? *	No
4	4. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	5. Anticipated timescale for follow-up FSN	N/A
4.	6. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	SD Biosensor, Inc.
	b. Address	C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
	c. Website address	http://www.sdbiosensor.com/
4.	7. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	8. List of attachments/appendices:	Customer/Distributor Verification Form
4.	9. Name/Signature	**QMR/Geun-kuk Song**
		 2020-12-22

	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.