



Date: 10, May, 2021

Attention: CTG China Trading GmbH

### Details on affected devices:

The affected products are come from Shenzhen Watmind Medical Co., Ltd. The name is SARS-CoV-2 Antigen Schnelltest zur Eigenanwendung (kolloidales Gold) and the type is Cassette.

**Description of the problem:**

After receiving inquiry from customers on swabs , we organized a self-examination and found that a certain number (500,000 units) of improper swabs were mixed into a batch of above mentioned kits with lot No.21040304. The swabs manufactured by Qingdao Yongqiang Huashang Medical Technology Co., Ltd are without “STERILE” mark printed on the package of the swabs. However, all the swabs actually being sterilized and no hazard for human body. Despite this, in order to reduce risk we determined to recall the defective products.

**Advise on action to be taken by the user:**

Please check the affected products in store, if find the same type and batch number's products, please isolate and mark immediately, and mustn't sell and use. Please contact the distributors or manufacturer to arrange the return. The distributor shall notify all customers who have purchased the defective batch number products to stop using immediately and help customers to return all unused products. Watmind will arrange to recall the defective batch number products.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact.

**Contact reference person:**

Name: Carrie Wu                      Organization: Shenzhen Watmind Medical Co., Ltd  
Address: 8th Floor, Building A, No.16-1, Jinhui Road, Jinsha Community, Kengzi Subdistrict,  
Pingshan District, 518118, Shenzhen, China  
Tel: +86-755-86969964              Mail: lirong.wu@watmind.cn

The under sign confirms that this notice has been notified the appropriate Regulatory Agency.

Signature:

Li Quan

Managing Director



Shenzhen Watmind Medical Co., Ltd.  
8th Floor, Building A, No.16-1, Jinhui Road, Jinsha Community, Kengzi  
Subdistrict, Pingshan District, 518118, Shenzhen, China

## Field Safety Notice

### Customer Acknowledgement Form

#### Field Safety Notice (FSN) information

FSN reference:	20210424-01
FSN Date:	10th, May, 2021
Product Name:	SARS-CoV-2 Antigen Schnelltest zur Eigenanwendung(kolloidales Gold)
Product Type:	Cassette
Affected Products:	Lot. 21040304 with improper swabs

#### Customer Details

Organization:	CTG China Trading GmbH
Address:	Immengarten 8, 30926 Seelze
Contact Name:	Daniel Zhao
Title or Function:	CEO
Telephone Number:	+49(0) 5137 9379197
Email Address:	service@medrhein.de

#### Customer Action Undertaken

tick					
	We confirm that we have received this FSN and ensure that all the contents are understood by those within our organization who need to be aware.				
	We confirm that we will distribute the information to all customers that have been supplied with the affected products.				
	We will perform all actions requested by the FSN.				
Print Name:		Signature:		Date:	

**Please return your completed and signed Acknowledgement Form within 5 working days to: [lirong.wu@watmind.cn](mailto:lirong.wu@watmind.cn)**