

FIELD SAFETY NOTICE

Details on affected devices:

Egoo SARS-CoV-2 Capsule, lot number 2201DD-01 to lot number 2202DD-01.

Description of the problem:

An empty or partly empty capsules was identified for Egoo SAS-CoV-2 Capsule. An empty capsule can provide a false negative result if sample material is added to the capsule.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. A negative result should always be combined with clinical observation, patient history, and epidemiological information.

Action to be taken by the user:

Scrap your Egoo SARS-CoV-2 Capsules (e48364) with lot number 2201DD-01 to 2202DD-01 within the next 5 days.

Contact reference:

e-mail:	Quality@egoo.health
Address:	Qlife Aps, Borupvang 3, 2750 Ballerup, Denmark
Phone	+4529684680

This notice should be passed on to all those within your organization who need to be aware of the issue and to any organization to which the potentially affected product(s) have been transferred.

Further assistance:

If you need assistance or have any questions regarding this notification, please contact us. We sincerely apologize for any inconvenience this may have caused to your laboratory.

Best regards,

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Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	18885
FSN Date*	2022-05-03
Product/ Device name*	SARS-CoV-2 Capsule
Product Code(s)	e48364
Batch/Serial Number (s)	2201DD-01 to 2202DD-01

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
<input type="checkbox"/> I confirm receipt of the Field Safety Notice and that I read and understood its content.		
<input type="checkbox"/> I performed all actions requested by the FSN.		
<input type="checkbox"/> I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
	N/A	Comments:
<input type="checkbox"/> No affected devices are available for destruction		
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	Quality@egoo.health
Postal Address	Borupvang 3, 2750 Ballerup, DK
Web Portal	https://www.egoo.health/
Deadline for returning the customer reply form*	2022-05-09

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.