



CUSTOMER LETTER

Add customer details

Ballerup 3may2022

Dear Customer

Qlife has recently become aware that empty capsules were identified in “Egoo SARS-CoV-2 Capsule”, identification e48364, manufactured between 220101 (YYMMDD) and 220228. The issue is related to a production error and is only related to lotnumbers from 2201DD-01 to 2202DD-01

Our records indicate that you have been invoiced for or have been shipped products with lot numbers which can have this problem.

Please understand the necessity of locating these products.

Please read the attached Field Safety notice below and act upon the actions required.

The Danish Medicines Agency has been notified about this field safety notice.

Thank you in advance for your assistance and prompt attention.
Qlife apologizes for any inconvenience resulting from this issue.

Best regards,
Qlife ApS

Senior QA / RA Specialist
Poul Erik Nielsen
Borupvang 3,
2750 Ballerup
Denmark
+4529684680

FIELD SAFETY NOTICE

Add customer details

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: **(example – distributor to insert contact)**

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,

(example – distributor to insert contact)

Senior QA / RA Specialist

Poul Erik Nielsen

Qlife aps

Borupvang 3,

2750 Ballerup

Denmark

Phone: +4529684680

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.

