

Van: meldpunt@igj.nl
Aan: [_Dienstpostbus IGJ Registratie](#)
Onderwerp: 2307 2825, FW: Re: New Gene Antigen REF: COVID-19-NG21 ?IT 5.1.2e
Datum: maandag 17 juli 2023 12:52:31
Bijlagen: [FSCA - IGJ - IT 5.1.2e .pdf](#)
[FSN - IGJ - IT 5.1.2e .docx](#)
[MIR_form - IGJ - IT 5.1.2e .pdf](#)
[Validation report.pdf](#)
[Letter of Statement\(1\).pdf](#)
[Letter of Statement\(1\)\(1\).pdf](#)
[FW Re New Gene Antigen REF COVID-19-NG21 IT 5.1.2e .eml](#)

Bijgaand bericht inboeken svp.

Aanvullende informatie FSCA

Objectnummer: 5.1.2e
 Referentienummer fabrikant: COVID-19-NG21
 Name of medical device or IVD: COVID-19-NG21

Tbv Afdeling Overstijgend, LMO Medische Technologie.
 IT: 5.1.2e

Met vriendelijke groet,

5.1.2e <meldpunt@igj.nl>

17-07-2023 09:59 Mailimport,: Sender: 5.1.2e @igj.nl
 Date sent: Jul 17, 2023 9:58 AM
 To: _Dienstpostbus IGJ Meldpunt <meldpunt@igj.nl>
 Subject: FW: Re: New Gene Antigen REF: COVID-19-NG21 ?IT 5.1.2e

Beste meldpunt,

Graag deze email en bijbehorende informatie inboeken onder IT 5.1.2e svp.
 Alvast bedankt.

Met vriendelijke groeten,

5.1.2e . 5.1.2e
 5.1.2e

.....
 afdeling medische technologie, team meldingen
 handreiking nieuwe regelgeving medische hulpmiddelen en invitro diagnostica

Inspectie Gezondheidszorg en Jeugd
 Ministerie van Volksgezondheid, Welzijn en Sport
 Stadsplateau 1 3521 AZ Utrecht
 Postbus 2518| 6401DA | Heerlen |Nederland

.....
 T +31 (0)88 1205000
 meldpunt@igj.nl
 www.igj.nl
 Twitter: @IGJnl LinkedIn IGJ

Duidelijk. Onafhankelijk. Eerlijk.

Van: [REDACTED]@sungoglobal.com <[REDACTED]@sungoglobal.com>

Verzonden: maandag 17 juli 2023 09:32

Aan: [REDACTED] [REDACTED] [REDACTED] <[REDACTED]@igj.nl>

CC: [REDACTED]@sungoglobal.com>

Onderwerp: Fw: Re: New Gene Antigen REF: COVID-19-NG21 ?IT [REDACTED]

[REDACTED]@sungoglobal.com

To [REDACTED] [REDACTED] [REDACTED]

Hide Detail

2023-06-12 15:40

From:

[REDACTED]@sungoglobal.com <[REDACTED]@sungoglobal.com>

To:

[REDACTED]
[REDACTED] [REDACTED]@fagg-afmps.be>

Cc:

[REDACTED]

Time:

Monday, 12 June 2023 (Mon) 15:40

Size:

5 MB

?

(2 MB)FSCA - IGJ - IT [REDACTED].pdf

?

(61 KB)FSN - IGJ - IT [REDACTED].docx

?

(207 KB)MIR_form - IGJ - IT [REDACTED].pdf

?

(503 KB)Validation report.pdf

?

(569 KB)Letter of Statement(1).pdf

?

(569 KB)Letter of Statement(1)(1).pdf

Dear [REDACTED]

We forwarded the questions in your email of May 17, 2023 to the manufacturer. It seems to us that the questions were inadvertently posed to SUNGO Global (our mother company, which has no role in this matter). The manufacturer asked us to submit the attached forms and statements.

1. FSCA

2. FSN

3. MIR

4. Validation report - Testing performance upon different volumes of liquid buffers.

5. Letter of statement from the manufacture.

Don't hesitate to contact us if you need more information.

Best regards,

5.1.2e

5.1.2e

5.1.2e

SUNGO Europe B.V.

T: 5.1.2e

E: 5.1.2e@sungoglobal.com

Fascinatio Boulevard 522, Unit 1.7,

2909VA Capelle aan den IJssel

The Netherlands

Sender: 5.1.2e@sungoglobal.com

Send Time: 2023-06-12 15:40

Receiver: 5.1.2e 5.1.2e

cc: 5.1.2e

Subject: Re: RE: New Gene Antigen REF: COVID-19-NG21 ?IT 5.1.2e

Dear 5.1.2e

We forwarded the questions in your email of May 17, 2023 to the manufacturer. It seems to us that the questions were inadvertently posed to SUNGO Global (our mother company, which has no role in this matter). The manufacturer asked us to submit the attached forms and statements.

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Don't hesitate to contact us if you need more information.

Best regards,

5.1.2e

Best Regards

Customer Service Team

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image001(06-12-1(07-17-09-10-27).jpg

M: 5.1.2e@sungoglobal.com

W: www.sungogroup.com/www.sungoglobal.com

With its offices in China, Europe, Australia and North America, SUNGO provides the technical solution for all the worldwide medical device manufacturers to meet the global regulation requirements.

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Sender 5.1.2e 5.1.2e

Send Time: 2023-05-17 11:43

Receiver: 5.1.2e@sungoglobal.com; 5.1.2e@fagg-afmps.be

Subject: RE: New Gene Antigen REF: COVID-19-NG21 ?IT 5.1.2e

Dear Sungo NL,

In reply to your email sent on May 1st 2023, the Health and Youth Care Inspectorate(IGJ) would like to make a few comments and ask some additional questions.

These questions related to our previous email about the test performance in low amount of buffer.

In your reply you wrote:

3.and 4. As a preliminary general remark, Sungo NL would like to state that the responsibility for any corrective action rests on the manufacturer (article 10, par. 12 MDR, and corresponding provision in IVDR) and that this responsibility can not be delegated to the authorized representative (article 11, par. 4 MDR).

Putting this formal consideration aside, Sungo NL is of the opinion that a field service corrective action (FSCA) as mentioned in your email, is not required in the present case. FSCA is a corrective action taken by a manufacturer for technical or medical reasons to either prevent or reduce the risk of a serious incident, which is associated with a device that is made available on the market. Given the reported deficiency (a lack of liquid in covid test tubes), the criteria for FSCA are not met, since it is not likely that the deficiency could cause a serious incident as defined in art. 2, par. 64 and 65 MDR (with corresponding provision in IVDR) and explained in MDCG 2023-3, clauses 2 and 14. We are therefore of the opinion that in the case you present in your email there might be an issue, but not a reportable problem.

The above are official reply of Sungo NL.

The IGJ would like to comment to the above:

Indeed, we agree the responsibility of the manufacturer cannot be delegated to the authorized representative (article 11, par. 4 MDR). However as an EU AR article 11, par. 3 (d, e, f (MDR)) clearly states and you are legally obliged to:

(d) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

(e) forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

(f) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that

is not possible, mitigate the risks posed by devices;

So IGJ has the opinion that:

- the rationale made by AR SUNGO NL should be the decision of SUNGO Global and
- as an AR has the responsibility to inform SUNGO Global about any request made by a competent authority of the Member State in which the authorised representative has its registered place of business.

Furthermore, we received from our Belgium colleagues from the FAGG also concerns related to this non conformity. They received similar complaints/incidents by end users. Furthermore they have the opinion this is not only related to a quality problem, but also a more general public health problem. If patients are confronted with a self-test with too little or no buffer fluid at all, it is unlikely that these patients will buy a new test. Or, in most cases they will perform the test with too little buffer liquid and will therefore get an incorrect result or will not perform a test at all.

The IGJ support the view of our Belgium colleagues. Not only the performance of the test in a decreased amount of buffer has not been validated, also the described general public risk of lay persons confronted with a self-test with too little or no buffer fluid is for the IGJ a potential safety risk and therefore meets the requirements of a 'field safety corrective action' i.e. means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market. Regarding the non-conformity, New Gene and SunGo both admit that in the lots an identified fault rate of 4.5-8% is unacceptable. However as a CA we have not seen any root cause investigation or action taken to resolve the situation/preventive measures by the manufacturer. Therefore the IGJ would like again to ask SUNGO:

- Could SUNGO Global provide evidence which demonstrates that specificity and performance of the test has not been affected in lots with decreased amount of buffer solution.
- If not, we kindly ask SUNGO Global to use this information to determine whether any market action is required for the device to resolve this non-conformity.
- If SUNGO determine no action is needed, please provide a rationale why SUNGO Global believes a (field safety) corrective action is not deemed necessary.

Best regards,

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5.1.2e

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 Medical Technology
 Health and Youth Care Inspectorate
 Ministry of Health, Welfare and Sport
 Stadsplateau 1 | 3521 AZ Utrecht
 Postbus 2518 | 6401 DA Heerlen

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 T 088 120 5000
 meldpunt@igj.nl
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 Twitter @IGJnl | LinkedIn IGJ

.....
 Clear. Fair. Independent.

Van: 5.1.2e@sungoglobal.com <5.1.2e@sungoglobal.com>

Verzonden: maandag 1 mei 2023 16:17

Aan: Dienstpostbus IGJ Meldpunt <meldpunt@igj.nl>; 5.1.2e 5.1.2e <5.1.2e@igj.nl>

Onderwerp: Re: New Gene Antigen REF: COVID-19-NG21 ?IT 5.1.2e

Health and Youth Care Inspection (Inspectie Gezondheidszorg en Jeugd)

Attn: 5.1.2e 5.1.2e

Re: IT 5.1.2e

Dear 5.1.2e

We received your email of 24 April, 2023, with the request to address the questions mentioned therein. In the same order, we reply as follows.

1.Sungo Europe BV (hereinafter Sungo NL, as in your email) is the registered authorized representative in EU for the product New Gene Antigen REF: COVID-19-NG21 from manufacturer New Gene Bioengineering Co. Ltd. (hereinafter: New Gene)

2.Sungo NL received few complaints from users about insufficient liquid in New Gene test kit tubes. To that extent, Sungo NL can confirm that it recognizes the issue mentioned in your email. Sungo has forwarded (all) these complaints to New Gene. As the complaints refer to individual cases, Sungo has no insight in and has no opinion on the overall percentage of deficient New Gene test kits.

3.and 4. As a preliminary general remark, Sungo NL would like to state that the responsibility for any corrective action rests on the manufacturer (article 10, par. 12 MDR, and corresponding provision in IVDR) and that this responsibility can not be delegated to the authorized representative (article 11, par. 4 MDR).

Putting this formal consideration aside, Sungo NL is of the opinion that a field service corrective action (FSCA) as mentioned in your email, is not required in the present case. FSCA is a corrective action taken by a manufacturer for technical or medical reasons to either prevent or reduce the risk of a serious incident, which is associated with a device that is made available on the market.

Given the reported deficiency (a lack of liquid in covid test tubes), the criteria for FSCA are not met, since it is not likely that the deficiency could cause a serious incident as defined in art. 2, par. 64 and 65 MDR (with corresponding provision in IVDR) and explained in MDCG 2023-3, clauses 2 and 14. We are therefore of the opinion that in the case you present in your email there might be an issue, but not a reportable problem.

The above are official reply of Sungo NL. In addition to this, the manufacture specifically mentions the following information for reference:

Specifically for this case, the company Protect and Care reached Sungo NL and New Gene before. New Gene has stated that they agree to compensate some products as after-sales which New Gene has always been taking care of, even without complete evidence locating the causes and responsibilities. Simply because the market demand is going down, the company Protect and Care requests only money than product replacement. The parties involved have been in discussion.

Don't hesitate to contact us if you need more information.

Best regards,

5.1.2e

Best Regards

Customer Service Team

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image001(06-12-1(07-17-09-10-27).jpg

M: 5.1.2e@sungoglobal.com

W: www.sungogroup.com|www.sungoglobal.com

With it's offices in China, Europe, Australia and North American, SUNGO provides the technical solution for all the worldwide medical device manufacturers to meet the global regulation requirements.

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permanently delete what you have received.

From: 5.1.2e 5.1.2e

Date: 2023-04-24 17:09

To: 5.1.2e @sungoglobal.com

CC: 5.1.2e @sungoglobal.com

Subject: New Gene Antigen REF: COVID-19-NG21

Dear Sungo,

The Health and Youth Care Inspectorate(IGJ) is the competent authority regarding medical devices and IVD in the Netherlands. The IGJ received from distributor Protect and Care B.V. a signal about a possible non-conformity in the New Gene Antigen REF: COVID-19-NG21 from manufacturer New Gene Bioengineering Co. Ltd. In detail, Protect and Care B.V. reports their findings with the New Gene Antigen REF: COVID-19-NG21 from manufacturer New Gene Bioengineering Co. Ltd. Protect and Care received the first complaints in October 2022 that there was not enough liquid in the sealed tubes.

Background

Protect and Care B.V. stated; Since the beginning of 2022, the distribution of the tests among our customers has started. In October 2022, we received a first complaint about these tests, which was based on the finding that there was insufficient liquid in the sealed tubes of the tests. We communicated this problem to our own supplier, Amann Trading & Consulting, who forwarded it to the manufacturer by email dated October 11, 2022. The latter responded that same day that it is very unlikely that the liquid would have evaporated as a result of an incomplete sealing of the container.

Since the beginning of 2023, Protect and Care B.V. reports they have seen an increase in complaints regarding the New Gene Covid tests from various customers. Therefore they further investigated this issue. A random check was carried out by an independent inspection and certification company SGS (BE), of which a report was subsequently drawn up (see attachment). This report has shown that on average 5-6% of the tests contain insufficient liquid to perform the test.

Protect and Care B.V. stated, I quote; We then turned to the European representative of the manufacturer, Sungo Global Service, who informed us by email of February 28, 2023 that she had heard such complaints about the New Gene Covid tests before. The European representative continued in his email as follows: "a fault rate for such self test kits should be less than 1%" and also subsequently informed the manufacturer. In an email, dated March 1 2023, the manufacturer confirmed that the reported problem is "abnormal": "The reported problem rate is actually high, which is quite abnormal." Protect and Care B.V. concluded that both the manufacturer and European representative themselves acknowledge that the margins of error set by them are exceeded.

As the CA of Lotus NL B.V., the IGJ would like to ask you the following:

Questions & actions

- Is Sungo NL the registered AR for the New Gene Antigen REF: COVID-19-NG21 from manufacturer New Gene Bioengineering Co. Ltd.?
- If so do you recognize the issue describe above?
- If so, we kindly ask SUNGO to use this information to determine whether any market action is required by you as the EU authorised rep. for the device.
- If SUNGO determine no action is needed, please provide a rationale why SUNGO believes a (field safety) corrective action is not deemed necessary.

Procedure

The inspectorate kindly requests you to address these questions, and respond not later than 1 week from the date of this e-mail. You can send your response by e-mail to meldpunt@igj.nl. Please refer to our reference number IT 5.1.2e when contacting us.

Any further questions?

I trust this provides you with sufficient information. If you have any questions, please do not hesitate to contact us. We are available from Monday until Friday, from 9.00 to 17.00 at +31 (0)88 7 120 50 00. You can also send an e-mail to meldpunt@igj.nl.

Best regards,

5.1.2e

5.1.2e

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Ministry of Health, Welfare and Sport
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