To: [redacted] Ministerie van VWS)'[redacted]@minvws.nl]
Cc: [redacted]@rivm.nl]
From: agtest
Sent: Fri 3/26/2021 1:20:29 PM
Subject: RE: Application for an exemption for a Antigen Rapid Test as a Self-Test | Santé Group
Received: Fri 3/26/2021 1:20:30 PM

Ha [redacted]

Dit dossier is nu compleet, we gaan ermee aan de slag. Het dossiernummer van ons is AG15.

Met vriendelijke groet,

[redacted]

[redacted]
National Institute for Public Health and the Environment (RIVM)
Centre for Health Protection (GZB)
PO Box 1
NL-3720 BA Bilthoven
[redacted]

Van [redacted] (Ministerie van VWS) <[redacted]@minvws.nl>
Verzonden: donderdag 25 maart 2021 14:53
Aan: [redacted]@rivm.nl>
CC: [redacted] (Ministerie van VWS) <[redacted]@minvws.nl>
Onderwerp: FW: Application for an exemption for a Antigen Rapid Test as a Self-Test | Santé Group

Beste collega's van het RIVM,

Hierbij stuur ik jullie de aanvullende (opgevraagd) documentatie voor het dossier van Santé Group.

Vriendelijke groet,
[redacted]

Van: [redacted]@sante-group.com>
Verzonden: donderdag 25 maart 2021 14:25
Aan: [redacted] (Ministerie van VWS) <[redacted]@minvws.nl>
CC [redacted]@sante-group.com>
Onderwerp: RE: Application for an exemption for a Antigen Rapid Test as a Self-Test | Santé Group

Dear [redacted]
Thank you for the update. Please see the attached Statement from MP Biomedicals.
If you could confirm that this document would suffice, that would be greatly appreciated.

Have a great day!

Thank you.

Warm Regards,

[redacted] • **sante-group.com** [redacted]

From: [redacted] (Ministerie van VWS) <[redacted]@minvws.nl>
Sent: 24 March 2021 21:33
To: [redacted]@sante-group.com>
Cc: [redacted]@sante-group.com> [redacted] Ministerie van VWS) <[redacted]@minvws.nl>
Subject: RE: Application for an exemption for a Antigen Rapid Test as a Self-Test | Santé Group

Dear 5.1.2e

Could you please provide us the following information:

- The CE declaration of conformity for any components not included in the professional test, if applicable. In case there is no difference between the professional test and the self test this is not necessary. In that case a clear statement that both products are identical would suffice.

Thank you in advance.

Kind regards,
5.1.2e 5.1.2e

5.1.2e (5.1.2e 5.1.2e
5.1.2e

Ministerie van Volksgezondheid, Welzijn en Sport
Directie Geneesmiddelen en Medische Technologie
Parnassusplein 5 | 2511 VX | Den Haag
Postbus 20350 | 2500 EJ | Den Haag

Email: 5.1.5 @minvws.nl

Van: 5.1.2e 5.1.2e < 5.1.2e @sante-group.com>
Verzonden: maandag 22 maart 2021 23:10
Aan: 5.1.5 Ministerie van VWS) < 5.1.5 @minvws.nl>
CC: 5.1.2e < 5.1.2e @sante-group.com>
Onderwerp: RE: Application for an exemption for a Antigen Rapid Test as a Self-Test | Santé Group

Dear 5.1.2e
Thank you for the update. Yes fully understand the amount of applications you must be getting at the moment!

If there's any other pieces of information/documents we need to provide, please let us know and we'll do so accordingly.

Look forward to any updates you have. Thanks!

Warm Regards,

5.1.2e 5.1.2e 5.1.2e • **sante-group.com** • 5.1.2e

From: 5.1.5 (Ministerie van VWS) < 5.1.5 @minvws.nl>
Sent: 22 March 2021 12:33
To: 5.1.2e 5.1.2e < 5.1.2e @sante-group.com>
Cc: 5.1.5 (Ministerie van VWS) < 5.1.5 @minvws.nl>
Subject: RE: Application for an exemption for a Antigen Rapid Test as a Self-Test | Santé Group

Dear 5.1.2e

Thank you for providing us the missing documents. We will proceed the assessment of your application.

Unfortunately, we cannot give you an expected date for a decision on your application. We are currently reviewing several requests for completeness and content. If we have any questions regarding your request we will contact you. We do our best to assess all requests as soon as possible.

We decide per application. One application takes more time than the other. As soon as a decision has been made, it will be published. The time of publication may therefore vary per application, there is not one specific date on which all decisions are announced.

Best regards,

5.1.2e

Ministry of Health, Welfare and Sport
Department of Pharmaceutical Affairs and Medical Technology
Parnassusplein 5 | 2511 VX | The Hague
P.O. Box 20350 | 2500 EJ | The Hague

Email: 5.1.5 @minvws.nl

Van: 5.1.2e 5.1.2e < 5.1.2e @sante-group.com>
Verzonden: maandag 22 maart 2021 12:35
Aan: 5.1.5 Ministerie van VWS) < 5.1.5 @minvws.nl>
CC: 5.1.2e < 5.1.2e @sante-group.com>; 5.1.2e < 5.1.2e @sante-group.com> 5.1.5 (Ministerie van VWS) < 5.1.5 @minvws.nl>
Onderwerp: RE: Application for an exemption for a Antigen Rapid Test as a Self-Test | Santé Group

Good Morning 5.1.2e

I trust you had a good weekend.
Please see the attached Dutch IFU. In addition, we have also received the "post-market surveillance plan" that our manufacturer has issued to complete the documentation package for the self-test EUA application.
Could we have a quick 10 minute teams meeting to understand the approval process and timescales?
Thanks! Look forward to hearing from you.

Warm Regards,

5.1.2e 5.1.2e 5.1.2e • **sante-group.com** • 5.1.2e

From: 5.1.2e 5.1.2e
Sent: 19 March 2021 16:36
To: 5.1.5 @minvws.nl
Cc 5.1.2e 5.1.2e @sante-group.com> 5.1.2e < 5.1.2e @sante-group.com>
Subject: RE: Application for an exemption for a Antigen Rapid Test as a Self-Test | Santé Group

Dear 5 5.1.2e ,

I hope you're well.
Thank you for your quick reply and initial feedback- please see my response below:

- I apologise that the zipped folder structure didn't open. I have rezipped it, so now it should work. The photos of the various components and packaging are included in Folder: 01_Self-Test, file numbers 07 and 08.
- To reply to your second point, please note the following statement:

> "Multiple clinical evaluations and studies have been carried out with the MP Bio SARS-CoV-2 rapid antigen test within Europe. These have been both trials organised by MP Biomedicals and also independent evaluations from institutes and government bodies including Bundesamt für Gesundheit (BAG), Department of Medical Sciences in Uppsala University, Department of Health and Social Care UK, and the Paul-Ehrlich institute. These studies from a wide range of European countries and across a broad timeframe all help to build a comprehensive case to prove the accuracy and performance of the test. This is relevant to the Dutch situation as it has been tested in-field in areas with similar Covid-19 prevalence in society as the Netherlands."

- With regards to the Dutch IFU, our lawyers are currently reviewing the newly translated documents, so if it's OK, I'll send that over to you tomorrow.

Thank you again for your work!

Have a lovely weekend.

Warm Regards,

5.1.2e 5.1.2e
5.1.2e
5.1.2e
Maxx House, Western Road, Bracknell, Berkshire, RG12 1QP
sante-group.com

santé next generation sourcing

From: 5.1.5 (Ministerie van VWS) < 5.1.5 @minvws.nl>
Sent: 18 March 2021 16:20
To: 5.1.2e 5.1.2e < 5.1.2e @sante-group.com>; 5.1.5 (Ministerie van VWS) < 5.1.5 @minvws.nl>
Cc: 5.1.2e < 5.1.2e @sante-group.com>; 5.1.2e 5.1.2e @sante-group.com>
Subject: RE: Application for an exemption for a Antigen Rapid Test as a Self-Test | Santé Group

Dear 5.1.2e

Thank you for your application for our derogation procedure.

I did a quick scan on whether your documentation is complete and there are at least a few documents missing.

- Clear (digital) illustrations or photos of the various components of the test and photos of the packaging from all sides and of the labels. An error occurred when I tried to open that particular zip-file.
- If the data used for validation is based on a study performed outside the Netherlands, explain how this data can be extrapolated to the Dutch situation.
- Instructions for use in Dutch. This is mandatory for all self-tests. If available: instruction videos in Dutch, and a link to or information about where these videos can be found.

Please provide us the missing documents and we will proceed the assessment of your application.

Best regards,

5.1.2e 5.1.2e 5.1.2e 5.1.2e
5.1.2e
Ministerie van Volksgezondheid, Welzijn en Sport
Directie Geneesmiddelen en Medische Technologie
Parnassusplein 5 | 2511 VX | Den Haag
Postbus 20350 | 2500 EJ | Den Haag
Email: 5.1.5 @minvws.nl

Van: 5.1.2e 5.1.2e < 5.1.2e @sante-group.com>
Verzonden: donderdag 18 maart 2021 09:45
Aan: 5.1.5 (Ministerie van VWS) < 5.1.5 @minvws.nl>
CC: 5.1.2e < 5.1.2e @sante-group.com>; 5.1.2e < 5.1.2e @sante-group.com>
Onderwerp: [WARNING: ATTACHMENT UNSCANNED] Application for an exemption for a Antigen Rapid Test as a Self-Test | Santé Group

Good Morning,

Following discussions with the Covid-19 Taskforce (5.1.5 @rivm.nl) we are applying for **an exemption for the offering of an antigen rapid test as a self-test based on Article 8 of the Medical Devices Act.**

After extensive liaison with our lawyers 5.1.2e and the manufacturer (MP Biomedicals GmbH), we have collated all the relevant documents necessary to apply for a derogation/exceptional use. The Word Document attached outlines where all the documents are located.

The following documentation is included:
Professional Use

- CE Marking/DoC documents for Professional Use Test.
- IFU Professional Use
- Clinical Evaluation Report (Paul Ehrlich Institute)
- Clinical Evaluation Report (MP Bio)
- Performance Characteristics Studies/Data
- Switzerland BAG Validation Confirmation
- Switzerland BAG Antigen Validation Evaluation
- Images of Professional Use Test
- COVID-19 Rapid Antigen Test EU Review List
- EU Commission COVID-19 IVD Device registration confirmation
- Italian MP Bio Antigen Test Registration

Self-Test

- Draft Declaration of Conformity
- ISO13485-2016 Certificate
- Self-Test Draft IFU
- Self-test Risk Mitigation documentation
- TÜV Notified Body self-test submission confirmation
- Self-test Evaluation Report (Lay Users)
- Self-test Kit Contents Presentation
- Pouch and Packaging document
- EU Notified Body Self-test application
- Czech Republic Authorization (Derogation
- BfArM Germany Acceptance of Application Self-test
- Promotional Flyer
- Essential Requirements Checklist

As stated above, we can confirm that this product has received a derogation for self-test in both Czechoslovakia and Germany (With proof documentation Attached). https://www.bfarm.de/DE/Medizinprodukte/Antigentests/_node.html. In addition, this test has been submitted to a notified body (TÜV), applying for a complete CE mark registration as a self-test device.

The total capacity for the MP Biomedicals test per week at current is 5.1.1c – however since it has derogations in 2 European countries already, and is close to getting a derogation in the UK, this capacity cannot be guaranteed for long. At current all documentation is provided in English, and can be professionally translated into Dutch if required.

The contacts for future questions about the application and the documentation:

- 5.1.2e 5.1.2e , 5.1.2e @sante-group.com, 5.1.2e
- 5.1.2e @sante-group.com, 5.1.2e

We'd appreciate confirmation of receipt of this email, any initial feedback, and would be happy to have a Teams meeting to answer any questions/provide further documentation to support this and expedite it as quickly as possible.

Warm Regards,

5.1.2e 5.1.2e
5.1.2e
5.1.2e
Maxx House, Western Road, Bracknell, Berkshire, RG12 1QP
sante-group.com

santé next generation sourcing