

To: [redacted] 5.1.2e [redacted] 5.1.2e @igj.nl
Cc: [redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e @minvws.nl; [redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e @minvws.nl; [redacted] 5.1.2e [redacted] 5.1.2e2 [redacted] 5.1.2e [redacted] 5.1.2e @minvws.nl; [redacted] 5.1.2e @minvws.nl; MedicalDevices (Ministerie van VWS) [redacted] 5.1.2e @minvws.nl
From: Medical Devices (Ministerie van VWS)
Sent: Tue 3/16/2021 2:54:20 PM
Subject: Ontheffingsaanvraag Acon Biotech
Received: Tue 3/16/2021 2:54:24 PM
[Exemptions application documents of antigen test from Acon Biotech.rar](#)

Beste collega's van de IGJ,

Hierbij stuur ik jullie een aanvraag door voor een ontheffing voor het gebruik van een antigeen sneltest als zelftest. De aanvrager is Acon Biotech.

De Europese gemachtigde is: MedNet GmbH, Borkstrasse 10,48163 Muenster, Duitsland.

Wij leggen de aanvraag graag ter aanvullend advies aan jullie voor.

Vriendelijke groet,

[redacted] 5.1.2e [redacted] 5.1.2e

[redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e
 [redacted] 5.1.2e

Ministerie van Volksgezondheid, Welzijn en Sport
Directie Geneesmiddelen en Medische Technologie
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 Email: [redacted] 5.1.2e @minvws.nl

Van: [redacted] 5.1.2e [redacted] 5.1.2e @aconlab.com.cn>
Verzonden: vrijdag 12 maart 2021 13:04
Aan: [redacted] 5.1.2e [redacted] 5.1.2e @minvws.nl>
CC: [redacted] 5.1.2e [redacted] 5.1.2e @aconlab.com.cn>; [redacted] 5.1.2e <[redacted] 5.1.2e @aconlab.com.cn>
Onderwerp: [WARNING : MESSAGE ENCRYPTED]Applying for an exemption to market a rapid antigen test as a self-test under section 8 of the Medical Devices Act- Acon Biotech

Dear Sir/Madam,

Subjects: Applying for an exemption to market a rapid antigen test as a self-test under section 8 of the Medical Devices Act

Good day!

This is [redacted] 5.1.2e from Acon Biotech(Hangzhou) Co. Ltd in China. We're an IVD manufacturer producing the SARS-CoV-2 diagnostic test. As a global company who has the IVD business all over the world for more than 25 years, we have good reputation in the IVD industry including U.S, Europe, Brazil, Canada, as well as many other countries.

We have developed a SARS-CoV-2 Antigen Rapid Test for professional use and distributed in the EU countries popularly. Now, to supply our SARS-CoV-2 Antigen Rapid Test products for self-test in Netherlands, we would like to apply for an exemption as per the **Procedure to obtain exemption for rapid antigen test for use as self-test** as published on your website. We have organized the documentation according to the requirements and attached for your assesment. Please kindly give your comments if any concern.

Please don't hesitate to contact me if you have any concern. Thanks for your time and looking forward to hear from you!

Best regards

[redacted] 5.1.2e

Acon Biotech (Hangzhou) Co., Ltd.
Tel: [REDACTED]
Fax: [REDACTED] 5.1.2e