

To: [5.1.2e] [5.1.2e] [5.1.2e] ([5.1.2e]) [5.1.2e] @minvws.nl; [5.1.2e] [5.1.2e] [5.1.2e] [5.1.2e]) [5.1.2e] @minvws.nl; [5.1.2e] [5.1.2e] [5.1.2e] [5.1.2e]) [5.1.2e] @minvws.nl
Cc: [5.1.2e] [5.1.2e] @minvws.nl; [5.1.2e] [5.1.2e] [5.1.2e] [5.1.2e]) [5.1.2e] @minvws.nl
From: [5.1.2e] [5.1.2e] @minvws.nl
Sent: Tue 3/16/2021 9:03:07 PM
Subject: FW: Ontheffingsaanvraag Wondfo
Received: Tue 3/16/2021 9:03:08 PM

Ter info, ditmaal zonder bijlagen.

Van: [5.1.2e] <[5.1.2e]@minvws.nl>
Verzonden: dinsdag 16 maart 2021 21:06
Aan: [5.1.2e] <[5.1.2e]@igj.nl>
CC: [5.1.2e] <[5.1.2e]@minvws.nl>
Onderwerp: Ontheffingsaanvraag Wondfo

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 Wondfo.

De Europees gemachtigde is Qarad BV, Cipalstraat 3 2440 Geel in België.

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

Vriendelijke groet,

[5.1.2e] [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: [5.1.2e]@minvws.nl

Van: [5.1.2e] <[5.1.2e]@wondfo.com.cn>
Verzonden: vrijdag 12 maart 2021 14:06
Aan: [5.1.2e] [5.1.2e] <[5.1.2e]@minvws.nl>
CC: [5.1.2e] [5.1.2e] <[5.1.2e]@wondfo.com.cn>; [5.1.2e] [5.1.2e] <[5.1.2e]@minvws.nl>
Onderwerp: Re:Re:Guangzhou Wondfo Biotech-Application for exemption to market a rapid antigen test as a self-test

Dear [5.1.2e]

Thanks for your quick response and sorry for bring you inconvinience.

Pls check the documents again. Hope it works this time.

Please feel free to let me know if you can not open the files again.

Best regards,

[5.1.2e]

Guangzhou Wondfo Biotech Co., Ltd

Stock Code: [5.1.2h]

Tel: +86 [5.1.2e]

E-mail: [5.1.2e]@wondfo.com.cn

Website: www.wondfo.com.cn ; POCT Manufacturer Leader (FDA, CE, TUV, ISO13485,ISO9001, FSC)

5.1.2e <5.1.2e@minvws.nl>
5.1.2e <5.1.2e@wondfo.com.cn> <5.1.2e@wondfo.com.cn>
5.1.2e <5.1.2e@wondfo.com.cn> <5.1.2e@minvws.nl>

发送时间:2021-03-12 18:57:09

主题:RE: Guangzhou Wondfo Biotech-Application for exemption to market a rapid antigen test as a self-test

Dear 5.1.2e

Thank you for your application. Unfortunately some of the documents that you have send are giving an error when I try to open it. The studies for lay person use both do not work. I have other tried other documents, which gave an error. Some others do function and I can open them.

Could you please resend the files, making sure that all the documents are accessible?

Thank you.

Kind regards,

5.1.2e 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: 5.1.2e @minvws.nl

Van: 5.1.2e @wondfo.com.cn <5.1.2e @wondfo.com.cn>

Verzonden: vrijdag 12 maart 2021 10:04

Aan: 5.1.2e <5.1.2e @minvws.nl>

CC: 5.1.2e <5.1.2e @wondfo.com.cn>

Onderwerp: RE: Guangzhou Wondfo Biotech-Application for exemption to market a rapid antigen test as a self-test

Dear Sirs or Madam,

This is 5.1.2e from Guangzhou Wondfo Biotech.I hope everything is well with you and your family .

Hereby on behalf of Guangzhou Wondfo Biotech, we are applying for an exemption to market a rapid antigen test as a self-test under section 8 of the Medical Devices Act.

Could you pls kindly help us check if the documents that we submitted meet the requirement of the exemption procedure?

Pls check the documents via wetransfer : 5.1.2h

Your prompt reply would be greatly appreciated.

Thank you!

PLS DOUBLE CHECK EMAIL ADDRESS AND WONDFO BANK ACCOUNT INFO BEFORE TRANSACTION

Best regards,

5.1.2e

Guangzhou Wondfo Biotech Co., Ltd

Stock Code: 5.1.2h

Tel: +86 5.1.2e

E-mail: 5.1.2e@wondfo.com.cn

Website: www.wondfo.com.cn ; POCT Manufacturer Leader (FDA, CE, TUV, ISO13485,ISO9001, FSC)