To: 5.1.5 (Ministerie van VWS)[5.1.5 @minvws.nl]; 5.1.2e . (5.1.2e) (5.1.2e @minvws.nl)[5.1.2e @minvws.nl]
From: 5.1.2e 5.1.2e 5.1.2e 5.1.2e)
Sent: Mon 3/22/2021 10:39:45 AM
Subject: RE: Potentially falsified Covid-19 test - AR in the Netherlands
Received: Mon 3/22/2021 10:39:45 AM

Lotus NL B.V. T.a.v. 5.1.2e Koningin Julianaplein 10 2595 AA 's-Gravenhage
Deze persoon is iig Europees gemachtigde. Ik heb mail gestuurd naar 5.1.2e

Van: 5.1.5 (Ministerie van VWS) < 5.1.5 @minvws.nl>
Verzonden: maandag 22 maart 2021 11:27
Aan: 5.1.2e 5.1.2e 5.1.2e 5.1.2e) < 5.1.2e @minvws.nl>
Onderwerp: FW: Potentially falsified Covid-19 test - AR in the Netherlands

Van: 5.1.2e 5.1.2e @fimea.fi>
Verzonden: maandag 22 maart 2021 11:16
Aan: 5.1.5 (Ministerie van VWS) < 5.1.5 @minvws.nl>
Onderwerp: Potentially falsified Covid-19 test - AR in the Netherlands

Dear Collegues,

I want to inform you about our attempts to contact authorized representative "Lotus NL B.V. from The Netherlands". I have not received responses from the authorized representative concerning potentially falsified device and/or illegal market claims of the Covid-19 test. The contact information of PRRC has picked up from EUDAMED actor module. Without AR response we are unable to confirm if Lotus is the authorized representative of this test and/or lay user market claims are from the distributor.

Please let me know if you additional information and have consider other activities if seen necessary. We will continue with the distributor in Finland.

Best regards,

5.1.2e
5.1.2e
Tel. 5.1.2e Mobile 5.1.2e
5.1.2e @fimea.fi

Fimea
Finnish Medicines Agency Fimea
P.O.Box 55, FI-00034 FIMEA, FINLAND | Tel. +358 5.1.2e | 5.1.2e @fimea.fi | Business ID: 0921536-6
www.fimea.fi | sic.fimea.fi | Twitter: @Fimea @Siclenti

From: 5.1.2e
Sent: maanantai 8. maaliskuuta 2021 13.24
To: 5.1.2e @lotusnl.com' <5.1.2e @lotusnl.com>
Subject: Authorised representative of Covid-19 Antibody Test Kit Limited Kit, Testsealabs Hangzhou Taixi Biotechnology

Dear 5.1.2e

Fimea as a competent authority in Finland has made aware that the test (Covid-19 Antibody Test Kit Limited Kit Testsealabs Hangzhou Taixi Biotechnology) has been falsely marketed as "Certified by the Finnish FIMEA" and that the test for professional use

has been marked for lay users In Finland. This is not acceptable. Finnish competent authority of medical devices do not certify medical devices.

Under section 11 of the Medical Devices Act in Finland, the marketing of medical devices may not be inappropriate, and it may not convey an exaggerated or false image of the device or its effectiveness or use. With regard to rapid Covid-19 test, the correct use and user group of the test should be clearly indicated in the marketing. In the marketing of tests intended for professionals, care must be taken to ensure that the marketing is targeted at healthcare professionals. The marketing must clearly indicate that a product intended for professionals is not suitable for at-home use and has not been proven to be safe and functional in layman use.

http://ksfamilyclub.de.mikecrm.com/vVjXKvD

Please find our requests below:

Are you EU representative of this test?
Please provide NB certificate if this is at-home test.
Please contact the distributor to correct the adulterated marketing claims

We expect a response by 15th **of March, 2021**

Best regards,

5.1.2e
5.1.2e
Tel. 5.1.2e Mobile 5.1.2e
5.1.2e @fimea.fi

Fimea
Finnish Medicines Agency Fimea
P.O.Box 55, FI-00034 FIMEA, FINLAND | Tel. +358 5.1.2e | 5.1.2e @fimea.fi | Business ID: 0921536-6
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