

To: [REDACTED] 5.1.2e @igj.nl
Cc: [REDACTED] 5.1.2e @minvws.nl; [REDACTED] 5.1.2e @minvws.nl; [REDACTED] 5.1.2e @minvws.nl; [REDACTED] 5.1.2e @minvws.nl
From: [REDACTED] 5.1.2e
Sent: Wed 3/10/2021 4:43:10 PM
Subject: Ontheffingsaanvraag Biosynex
Received: Wed 3/10/2021 4:43:16 PM
[Summary of BIOSYNEX dossier-Covid-19 Ag self-test.pdf](#)
[Document 1A Declaration of conformity BIOSYNEX COVID-19 AgBSS PROFESSIONAL VERSION.pdf](#)
[Document 1B Statement of equivalence professional and self-testingversion.pdf](#)
[Document 1C Device Description including Variants COVID-19Ag PROFESSIONAL and SELF-TEST.pdf](#)
[Document 2 Order Confirmation TUV SUD COVID-19 Antigenself-test BIOSYNEX.pdf](#)
[Document 3 Bill Of Materials Covid-19 Ag self test.pdf](#)
[Document 4A Product Verification and Validation AnalyticalPerformances COVID Ag professional and self test.pdf](#)
[Document 4B Product Verification and Validation ClinicalPerformances COVID Ag professional and self test.pdf](#)
[Document 4C Status validatie SARS-CoV-2 antigeensneltesten 8 februari2021.pdf](#)
[Document 5 Laymen study-COVID-19 Ag SELF TEST.pdf](#)
[Document 6A KIT 859256 ML V02202103R01-Box design 1 test per kit.pdf](#)
[Document 6B KIT 859261 ML V01202103R01-box design 5 tests per kit.pdf](#)
[Document 6C IFU 859256 ML V01202103R01 Instructions For Use.pdf](#)
[Document 7 IFU SW40006 NL V08202103R01 PROFESSIONAL TEST.pdf](#)
[Document 8 Essential Principles Checklist COVID-19 Ag SELF TEST.pdf](#)
[Document 9A Risk management file COVID-19 Ag PROFESSIONAL and SELFTEST.pdf](#)
[Document 9B DOC 3A Annex I Risk assessment & risk control COVID Ag rev4PROFESSIONAL and SELF TEST.pdf](#)
[Document 10 Seznam-antigennich-testu-pro-ktere-vydalo-ministerstvo-vyjimku-.pdf](#)
[Health Security Committee list adopted on 17 February 2021.pdf](#)

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 Biosynex.

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

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 @biosynex.com>

Verzonden: woensdag 10 maart 2021 16:49

Aan: Medical Devices (Ministerie van VWS) <[REDACTED] 5.1.2e @minvws.nl>

CC: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @biosynex.com>; [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @de-korte.tel>

Onderwerp: Object : Exemption for the provision of an Antigen Rapid Test as self-test according to Article 8 of the Law BIOSYNEX submission

Urgentie: Hoog

Dear Madam/Sir,

In reference to the publication on March 4, 2021 of "Procedure voor ontheffing voor antigeen sneltest als zelftest" by the Ministry of VWS, we, **BIOSYNEX SWISS SA** as legal manufacturer of BIOSYNEX COVID-19 Ag BSS rapid test (reference SW40006- for professional users), would like to apply for obtaining a temporary exemption for the usage of this rapid antigen test for the detection of SARS-CoV-2 as self-test in The Netherlands.

Please find attached BIOSYNEX letter which is a summary of our application dossier. I also attach in this e-mail 17 documents which are well identified in the application summary, from Document 1A to Document 10.

Please note also that our product BIOSYNEX COVID-19 Ag BSS (professional) is included in the most recent version of the Health Security Committee list adopted on 17 February 2021 "A common list of COVID-19 rapid antigen tests" .

On behalf of BIOSYNEX company, I thank you very much in advance for reviewing our application.

Please contact us if there are any questions about the submitted documentation.

We look forward to the opportunity of making our products accessible in support of the response to the COVID-19 pandemic in The Netherlands.

Cordialement,
Best regards,

BIOSYNEX

www.biosynex.com



Vered MALKA
Quality Assurance & Regulatory affairs officer

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