Ministry of Health, Welfare and Sport

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Information
Gela, Z. (Zarife)
medicaldevices@minvws.nl

Our reference
1852509-220466-GMT

Your reference

All correspondence addressed to the postal address quoting date and reference of this letter.

Date	March 31, 2021
Subject	Decision exemption Acon Biotech

Dear Mrs. Lu,

On behalf of Acon Biotech (hereafter: the applicant) you submitted an application on 12th of March 2021 for an exemption under section 8 of the Medical Devices Act (WMH) for the Flowflex SARS-CoV-2 Antigen Rapid Test.

This letter contains the decision concerning your application.

Assessment of your application

Having assessed the documentation that you submitted, I find as follows:

- You are a manufacturer of an antigen test and are able to demonstrate that the rapid antigen test in question already bears a CE-mark for professional use.

- You have demonstrated that you have submitted an application to a notified body of one of the EU member states to obtain CE-certification for use of the rapid antigen test as a self-test.

- I asked the Health and Youth Care Inspectorate (hereafter: IGJ) to provide a supplementary opinion on your application. The purpose of this limited check is to determine whether there are any with respect to factors that would advise against the manufacturer of the antigen self-test. In the context of this limited check, the IGJ did not find any factors that would advise against the manufacturer or the product.

- In addition, I asked the National Institute for Public Health and the Environment (RIVM) for its opinion on your application. As part of the procedure in which the Ministry of Health, Welfare and Sport (VWS) grants temporary exemptions under the exceptional circumstances of the COVID-19 pandemic, RIVM conducts a limited assessment of certain sections of each complete application. These are the product description, instructions for use, user-friendliness study, risk management, validation studies and the checklist of essential requirements. This assessment is not comparable

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with an assessment in the context of the requirements for CE certification. Consequently, the manufacturer may not use RIVM's assessment to invoke any rights in a certification procedure with a notified body.

- The final conclusion of RIVM's assessment of the Flowflex SARS-CoV-2 Antigen Rapid Test: The test is fundamentally sound. However, RIVM recommends that the manufacturer be required to make a number of changes to the instructions for use. These changes are mentioned in the Annex to this decision (in Dutch).

Decision
On the basis of the assessment and the opinions provided by the IGJ and RIVM, I have decided as follows:

Pursuant to section 8, subsection 1 and section 9, subsection 1 of the WMH, and subject to the conditions stated below, I hereby grant Acon Biotech an exemption from the provisions in article 3, paragraph 1 and article 7 of the Decree on *in vitro* diagnostic medical devices (IVDs) with respect to making available and distributing the Flowflex SARS-CoV-2 Antigen Rapid Test as a self-test for which no CE certificate has (yet) been issued. The exemption is valid until 31 December 2021 at the latest.

- The exemption applies exclusively to the territory of the Netherlands.
- The exemption will enter into effect on 1st of April 2021 and will remain valid until 31 December 2021 at the latest.
- If a notified body issues an EC design-examination certificate for the use of this test as a self-test before 31 December 2021, the manufacturer must inform the Ministry of Health, Welfare and Sport and the IGJ immediately by emailing a copy of the EC design-examination certificate to medicaldevices@minvws.nl. In that case, the exemption will be lifted with immediate effect. Tests that have already been placed on the market under the exemption may be sold to users and used.
- Your rapid antigen test satisfies the requirements for devices for self-testing as set out in the Decree on *in vitro* diagnostic medical devices (IVDs) and existing standards for self-tests (with the exception of the EC design-examination certificate for self-tests, issued by a notified body).
- If, after completing the conformity assessment procedure, the notified body concludes that the test does not comply with the statutory requirements for self-tests and does not issue a certificate, you must inform the Ministry of Health, Welfare and Sport and the IGJ immediately by sending an email to medicaldevices@minvws.nl.
- The manufacturer must promptly provide the IGJ, at its request, with comprehensive information about all incidents involving the product (or use of the product), in addition to the procedures already in place.
- The applicant must comply with the regular statutory vigilance procedures relating to general safety and performance requirements.
- Any reports of incidents and safety issues related to self-administering the test in question must be reported immediately to the IGJ.
- You are able to record and assess experiences with the use of the rapid antigen test as a self-test and, on the basis of this information, are able to indicate appropriate measures to the manufacturer or the authorised representative in the EU, if necessary. You have made written agreements

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with the manufacturer and, if applicable, its authorised representative in the EU, concerning compliance with statutory requirements regarding post-market surveillance and are able to present these agreements immediately upon request.

- In the instructions for use you must include contact details so that users can report a complaint about or incident involving the test.
- The instructions for use must clearly state that the user should not take any decision of medical relevance without first consulting his or her medical practitioner.
- The instructions for use must contain the instructions for the user laid down by the government. These instructions must explain the steps to be taken in response to a negative or positive test result. These instructions (in Dutch) can be found on the central government website.[1]
- Depending on how the pandemic develops, the Ministry of Health, Welfare and Sport may decide to amend these instructions at any time. In that case, you will receive further information.
- If you wish to make any change that relates to the essential requirements the test must meet, including specifically the labelling (outer packaging and instructions for use), you must explain this change to the Ministry of Health, Welfare and Sport in an email to medicaldevices@minvws.nl.
- This decision will be published on www.rijksoverheid.nl/ontheffingen-antigeentesten. If a notified body issues an EC design-examination certificate for the use of this test as a self-test, the exemption will be removed from the website.
- You must state on the individual packaging and/or in the supplemental instructions that the Flowflex SARS-CoV-2 Antigen Rapid Test has been placed on the market under the exemption granted to you and refer to the website where the decision is published. This information can be given by means of a label or sticker on the packaging stating the name of the applicant and referring to the website where all exemptions are published, or in the supplemental instructions stating the steps to be taken in response to a negative or positive test result.
- You must make the changes to the instructions for use as mentioned in annex I of this decision.

Yours sincerely,
the Minister of Medical Care and Sport,
on behalf of
the Director of the Department of Pharmaceutical Affairs and Medical Technology,

dr. M.T.M. van Raaij

[1] Informatie voor gebruiker van corona zelftest (Information for coronavirus self-test users)| Publicatie | Rijksoverheid.nl