Ministerie van Volksgezondheid,
Welzijn en Sport

Procedure to obtain exemption for rapid antigen test for use as self-test

As of 4 March 2021 manufacturers and distributors of rapid antigen test kits can apply for a temporary exemption to market their product as a self-test in the Netherlands. There are currently no rapid antigen tests that bear CE-marking for use as a self-test. But the government wants to facilitate self-testing and make the kits available on the market quickly, safely and responsibly. Manufacturers can therefore apply for a temporary exemption to bring rapid antigen self-test kits to the Dutch market more quickly. Granted exemptions will initially be valid until 31 December 2021 and will be published on rijksoverheid.nl.

Conditions and criteria for the exemption procedure

To obtain an exemption for a rapid antigen test, a manufacturer or distributor must satisfy the following conditions and criteria:

Specific

- The applicant must be able to demonstrate that the rapid antigen test in question already bears a CE-mark for professional use.
- The applicant must be able to demonstrate that they have already started a conformity assessment procedure with a notified body to obtain a CE-mark for the use of the rapid antigen test as a self-test.
- The suitability of the rapid antigen test as a self-test has been demonstrated for a specifically defined target group.
- The 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 design-examination certificate for self-tests, issued by a notified body).

General

- All documentation must be supplied in English or Dutch.
- The application must include the contact details of an individual to whom questions about the application and the documentation can be directed.
- The application must state if the rapid antigen test is included in the most recent version of the Health Security Committee's 'A common list of COVID-19 rapid antigen tests',[1] published on 17 February 2021.
- The application must state whether another EU member state has already granted an exemption for use of the rapid antigen test as a self-test.
- The submitted file must have a clear structure and a table of contents and must be easy to search.
- The applicant must have a post-market surveillance system in place for recording and assessing experiences with using the rapid antigen test as a self-test, based on which appropriate measures can be taken if necessary.[2]
- Any reports of incidents and safety issues related to self-administering the test in question must be reported immediately to the Health and Youth Care Inspectorate (IGJ).
- The applicant must comply with the regular statutory vigilance procedures relating to general safety and performance requirements.

[1] https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf.
[2] Article 8, paragraph 5 of the IVD Decree on conformity assessment procedures, and Annex III, article 5, Annex IV, article 3, paragraph 1 and Annex VI, article 3.

- If the applicant obtains a CE-mark for use of the rapid antigen test as a self-test, they must inform IGJ and the Pharmaceuticals and Medical Technology Department (GMT) of the Ministry of Health, Welfare and Sport via medicaldevices@minvws.nl.
- Exemptions granted are published on rijksoverheid.nl.
- While processing the application, the Ministry of Health, Welfare and Sport may request supplementary documentation or make changes if necessary. Applicants will be informed in good time and will have an opportunity to amend their application where necessary.

Documentation requirements

- The following documents must in any case be included with an application for exemption:
- Evidence that the rapid antigen test bears a CE-mark for professional use, including the supporting documentation.
- Evidence that an application has been submitted 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. Alternatively, evidence that a contract has been signed for a conformity assessment procedure via a notified body of one of the EU member states for use of the rapid antigen test as a self-test, including a confirmed plan of action with a timetable for obtaining CE-certification (if available).
- Product information:
    - Product name/trade name and catalogue number.
    - General description of the test and how it works.
    - Intended use of the test, including type of sample/sampling method and description of the testing target group.
    - Clear (digital) illustrations or photos of the various components of the test and photos of the packaging from all sides and of the labels.
    - Validation studies: reports of analytical and clinical validation studies (describing methods and results) into the test's performance when self-administered without supervision (sensitivity and specificity).
    - If the data used for validation is based on a study performed outside the Netherlands, explain how this data can be extrapolated to the Dutch situation.
    - Validation studies: reports of analytical and clinical validation studies (describing method and results) into the test's performance when administered professionally (sensitivity and specificity).
    - Study into user-friendliness of the rapid antigen test when self-administered, taking due account of the requirements set out in EN-IEC62366-1.
    - Instructions for use in Dutch. This is mandatory for all self-tests. If available: instruction videos in Dutch, and a link to or information about where these videos can be found.
    - Description of the test kit components (device, reagents, accessories) needed for administering the self-test, as well as a description of differences compared to the original test for professional use; the names of suppliers of the individual components must also be provided.
    - The CE declaration of conformity for professional use of the rapid antigen test.
    - The CE declaration of conformity for any components not included in the professional test, if applicable.
    - Checklist of essential requirements.
    - Risk management documentation, including an overview of risk estimation, risk control measures and residual risks, in accordance with EN ISO 14971. Clearly indicate any risks connected specifically to using the test as a self-test, for example by highlighting the relevant passages.
- If applicable: provide evidence that another EU member state has already granted an exemption for use of the rapid antigen test as a self-test.
- The instructions for use must contain the instructions laid down by the government, and explain the steps to be taken in response to a negative or positive test result, respectively (more information on this will follow).

The application for an exemption can be sent to medicaldevices@minvws.nl. In the email, state that you are **applying for an exemption to market a rapid antigen test as a self-test under section 8 of the Medical Devices Act**. The application must be accompanied by the required documentation (see above).