14th January 2021

Importers, distributors and would-be distributors of SARS-CoV2 (Covid-19) tests

General

Because of the coronavirus situation in Finland and around the world, a lot of new products are rapidly entering the market. In particular, the number of rapid Covid-19 tests on the market has quickly increased, and many new operators have emerged in the field.

Rapid tests and other tests intended for diagnosing coronavirus are so-called *in vitro* diagnostic (IVD) medical devices. In Finland, such devices governed by the Medical Devices Act (629/2010) that implements Directive 98/79/EC as amended. The Finnish Medicines Agency Fimea is the competent authority for medical devices.

With this letter, Fimea provides operators with information and reminds them of the requirements concerning Covid-19 tests and their appropriate marketing. Additionally, Fimea requests additional information about the tests currently on the market.

Conformity and CE marking

Only medical devices that are in conformity with the legal requirements may be placed on the market and put into service in Finland and in the EU area. Before placing a product on the market, the manufacturer is required to demonstrate its safety, suitability for the intended use and performance. The intended use defines the risk category of the product. The risk category determines the assessment procedures the manufacturer is required to comply with for the demonstration of conformity. For example, an assessment by an external inspection body, a 'notified body', is always required for an at-home SARS-CoV2 test.

A CE marking is the manufacturer's declaration that the product is in conformity with the applicable requirements. In addition to the CE marking shown on the packaging, product and instructions for use, the manufacturer must prepare a Declaration of Conformity (DoC). As a rule, the free movement of goods in the EU area applies to medical devices that bear an appropriate CE marking.

Registration of the operator and the product

Manufacturers and authorised representatives established in Finland are required to notify both their contact details and the medical devices they manufacture or represent to Fimea's medical device register. Currently, distributors or importers of CE marked tests intended for professional use are not required to file a separate medical device register notification with Fimea.

Mannerheimintie 166, Helsinki | P.O. Box 55, 00301 Helsinki | Tel. (09) 473 341 | Fax (09) 714 469
kirjaamo@fimea.fi | www.fimea.fi | Business ID 0921536-6

However, any devices intended for **self-testing** imported to Finland and the operator's contact details (at-home tests) must always be notified to Fimea's medical devices register.
https://www.fimea.fi/laakinnalliset_laitteet/laakinnallisen-laitteen-markkinoille-saattaminen/rekisteroinnit
https://www.fimea.fi/web/en/medical-devices/registration.

It must be noted that following the implementation of the EU's new IVD Regulation (2017/746), the registration of operators and products will take place in the common European EUDAMED database. Further information is available on the Fimea website at: https://www.fimea.fi/web/en/medical-devices
(https://www.fimea.fi/laakinnalliset_laitteet/eudamed-tietokanta/toimijoiden-ilmoittamisvelvollisuus).

Import of devices from outside the EU

If the manufacturer is based outside the EU, it is required to have an authorised representative in Europe (AR/EC Rep). The authorised representative in Europe registers the product with the competent authority of their country. Information about the authorised representative in Europe must be included in the instructions for use and/or packaging of the test, as well as in the DoC. Under the EU medical device legislation, the authorised representative in the EU represents the manufacturer in all regulatory matters within the EU/EEA. An authorised representative is not the same as the manufacturer's commercial representative.

Because European authorities have recently become aware of several non-conforming tests and even falsified information, Fimea requests all distributors to check with the authorised representative that the registration has been duly carried out and that an appropriate agreement has been concluded between the manufacturer and the authorised representative. Distributors should also check that the instructions for use and the packaging include appropriate information about the manufacturer and the CE marking. Furthermore, information about the authorised representative must be provided at least on the packaging or in the instructions for use.

Language requirements

There are country-specific language requirements for the instructions for use and labelling within the EU/EEA. In Finland, the instructions for use of a test intended for professional health care users can be provided in Finnish, Swedish or English, excluding the instructions necessary for safe use, which must be provided in Finnish and Swedish. Based on a risk assessment, the manufacturer assesses what information is considered necessary for safe use. The instructions for use for IVD devices intended for **self-testing** (at-home tests) must always be provided in Finnish and Swedish.

Reporting of adverse incidents

According to section 17 of the Medical Devices Act, the operator shall notify the manufacturer or authorised representative of any adverse incidents it has become aware of that have been confirmed, or are suspected of, having resulted from a defect or shortcoming in the device or its labelling.

This means that if the distributor or importer becomes aware, for example, by way of a customer complaint, of a suspected adverse incident or malfunction related to the test, this must be immediately communicated to the manufacturer so that the manufacturer can take the necessary steps to determine and investigate the causes that resulted in the adverse incident. The manufacturer or authorised representative is obliged to inform the authority of the incidents.

Traceability

Should any problems or risks related to the product arise, it is important that the products can be traced throughout the supply chain. Examples of such situations include the recall of a defective product batch by the manufacturer and other urgent safety notices. The competent authority may also need detailed information about the distribution chain for market surveillance purposes.

Fimea advises all operators to ensure the traceability of their products throughout the supply chain. In particular, we would like to draw attention to the distribution chain of at-home tests.

At-home tests

An at-home test (i.e. a device intended for self-testing) is a test specifically intended by the manufacturer for layman use and that has been demonstrated to be safe and effective for in this use.

An assessment by an external inspection body, a ‘notified body’, is always required for an at-home test. If the product is intended for at-home use, this is indicated in the instructions for use, in the DoC and in the separate certificate issued by the notified body. In this case, the four-digit code of the notified body that evaluated the product must also be shown next to the CE marking (CE XXXX).

Products intended for self-testing (at-home tests) imported to Finland must be notified to Fimea’s medical devices register (see section ‘Registration of the operator and the product’ above).

The marketing of at-home tests is discussed in more detail below under section ‘Marketing’.

The Finnish Institute for Health and Welfare (THL) has prepared more detailed instructions for at-home testing for citizens (see section Further information). The web page will be available when conforming at-home tests are placed on the market in Finland. The instructions explain, in layman’s terms, what to do with negative or positive test results obtained from at-home tests.

Importers and distributors of at-home tests are strongly recommended to provide their customers with information about THL's additional instructions upon purchase of the at-home test. The provision of the instructions to the end user can be carried out by means of a hardcopy or electronic announcement given in connection with the supply of the product. The manufacturer can also append information about the additional national instructions to the product’s instructions for use. The information provided to

the customer does not have to include THL's guidelines in their entirety; it is sufficient that the customer is referred to the up-to-date national instructions.

Repackaging of, or other changes to, the product

A medical device is an entity of which appropriate package labelling and instructions for use are an integral part. The manufacturer is responsible for the whole of the medical device placed on the market.

Under section 17 of the Medical Devices Act, the operator (for example, a distributor or importer) shall ensure that, when providing a medical device to an end user, the device is in the condition in which the manufacturer has intended the device to be used.

Consequently, the operator cannot independently repackage the product into smaller batches, for example, or modify or translate the instructions for use without the manufacturer's approval, or change the package labelling with regard to the product name, intended use or other information.

Even if agreed with the manufacturer that marketing will be carried out under the distributor's own product name, the manufacturer is always responsible for the product. The manufacturer and the manufacturer's contact details must always be clearly indicated on the packaging and in the instructions for use. The manufacturer's declaration of conformity shall also cover the product sold under a new product name.

Starting from 26 May 2022, repackaging and other similar measures will be regulated through the IVD Regulation (see Regulation 2017/746, Article 16 for further details).

Marketing

Under section 11 of the Medical Devices Act, 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.

The manufacturer's and THL's instructions on the use of the results of at-home tests and the verification of the results by means of a laboratory test as applicable must be taken into account in the marketing* of at-home tests. A negative at-home test result does not, for example, relieve the person concerned from the quarantine ordered by an authority or allow a person with symptoms to engage in activities outside of their home.

*Marketing means any provision of information, order acquisition and incentive measures aimed at promoting the prescription, supply, purchase or use of a device

Prerequisites of Covid-19 testing activities

In the marketing of tests intended for professionals, it should also be noted that in Finland, SARS-CoV2/COVID19 testing, like any other patient sample diagnostics intended for diagnosing communicable diseases, is subject to licence in accordance with the Communicable Diseases Act (1227/2016) and that the healthcare unit carrying out the tests must have a clinical microbiology licence. Furthermore, a private healthcare service provider must have a licence to provide the services issued by an authority (Private Health Care Act 152/1990).

Further information

More information about placing medical devices on the market is available on our website at: https://www.fimea.fi/web/en/medical-devices/placing-on-the-market (https://www.fimea.fi/laakinnalliset_laitteet/laakinnallisen-laitteen-markkinoille-saattaminen).
The page also contains a link to current legislation on medical devices: https://www.fimea.fi/web/en/medical-devices/legislation
(Please see pages in Finnish for more comprehensive information: https://www.fimea.fi/laakinnalliset_laitteet/laakinnallisiin-laitteisiin-liittyva-lainsaadanto.)

THL's instructions for citizens on at-home tests:
thl.fi/koronakotitesti *Web page will become available, when Fimea receives the first notification of placing on the market of a device for self-testing*.

Further information about different test types:
https://thl.fi/en/web/infectious-diseases-and-vaccinations/what-s-new/coronavirus-covid-19-latest-updates/symptoms-and-treatment-coronavirus/coronavirus-tests

https://www.fimea.fi/web/en/about_us/whats_new/coronavirus-covid-19-/frequently-asked-questions-covid-19-

Requirements for testing:
https://avi.fi/en/services/businesses/licences-notices-and-applications/social-welfare-and-health-care/private-health-care/clinical-microbiology-laboratories

Actions for the importer and distributor of Sars-CoV2/Covid-19 tests

We urge distributors to ensure the conformity and appropriate marketing of products in line with what is described above.

To provide Fimea with a comprehensive picture of all SARS-CoV2/COVID-19 tests available on the market in Finland, we kindly ask you to send the following documents to Fimea (laiteinfo@fimea.fi or medicaldevice@fimea.fi), unless you have already done so:

1. Declaration of Conformity
2. Instructions for use
3. Images of the package and device labelling

4. For at-home tests, a certificate issued by the notified body that assessed the test; and
5. In accordance with the normal practice, we also ask you file a medical device register notification of at-home tests with Fimea.

Note: the submission of information to Fimea is not a licencing or application process. The distributor or importer of a conforming device need not wait for Fimea's acknowledgement or approval before commencing the operations. Fimea uses the information in its market surveillance. Where necessary, Fimea will contact you if any questions arise on the basis of the submitted information.

If you need additional information or if you are offered products for sale the conformity of which is uncertain, please contact us.

Thank you for your cooperation.

Kind regards,

Heikki Mattlar
Head of Unit (Medical Devices)

For more information, please contact:

Nelli Karhu
nelli.karhu@fimea.fi

Hanna Valo
hanna.valo@fimea.fi