1 September 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. The Finnish Medicines Agency (Fimea) is the competent supervisory 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.

This letter (v. 3.0) has been updated to reflect the requirements of the new national legislation that entered into force in July 2021 and the changes made to the Fimea website. The changes concern the instructions and fees related to the registration of new operators. In addition, the letter highlights a number of changes related to the application of the European IVD Regulation that will enter into force in 2022.

Regulation

In Finland, IVD devices are regulated by the Act on Certain Medical Devices Specified in EU Directives 629/2010 that implements EU Directive 98/79/EC as amended. The Act on Certain Medical Devices Specified in EU Directives was formerly known as the Medical Devices Act that was amended in July 2021. Additionally, IVD devices are regulated by the EU IVD Regulation (2017/746) and the new national Medical Devices Act 719/2021.

The regulation of IVD devices at the European and national level is currently in transition. Until the date of full application of the new European IVD Regulation (26 May 2022), regulation will take place in Finland under the EU Regulation and two national laws. **Until the application of EU Regulation 2017/746, the regulation related to coronavirus tests is laid down in the Act on Certain Medical Devices Specified in EU Directives 629/2010, with the exception of registrations and so-called professional use, the regulation of which is included in the Medical Devices Act 719/2021.** However, the IVD Regulation and the Medical Devices Act are already applied to devices *in conformance with the IVD Regulation* that were placed on the market prior to the date of application of the IVD Regulation (26 May 2022).

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- Act on Certain Medical Devices Specified in EU Directives
- Medical Devices Act 719/2021
- IVD Directive 98/79/EC
- EU IVD Regulation 2017/746.

(*Both Acts in Finnish. English translations pending, please check our webpages for updates on translations: https://www.fimea.fi/web/en/medical-devices*)

Information about the legislative changes is available on our website: https://www.fimea.fi/web/en/-/laws-supplementing-eu-regulations-on-medical-devices-come-into-force

Conformity and CE marking

Only medical devices that are in conformity with the 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 verify 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 in the demonstration of conformity. For example, an assessment by an external inspection body, a 'notified body', is always required for a SARS-CoV2 self-test (at home test).

A CE marking is the manufacturer's proof 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.

Furthermore, those who import tests to Finland and their distributors are required, with certain exceptions, to notify their contact details and the medical devices they represent to Fimea's medical device register. When notifications of self-tests are submitted, their instructions for use, package labelling, declaration of conformity and the certificate issued by a notified body shall also be submitted to Fimea.

The notification procedure and the information to be enclosed with the notification are described in further detail in Fimea's Administrative Regulation 2021/2.
Guidance and operator and device registration forms:
https://www.fimea.fi/laakinnalliset_laitteet/laakinnallisen-laitteen-markkinoille-saattaminen/rekisteroinnit
(*English translations pending, please check our webpages for updates on translations*: https://www.fimea.fi/web/en/medical-devices)

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

Note: The submission of information on a self-test to Fimea is not a licencing or application process. The registration of an operator or product does not imply any approval or authorisation of that operator or its medical devices by Fimea. Any marketing claims about an operator or device being approved by Fimea or the EU are considered misleading.

Imports of devices from outside the EU and authorised representative in 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 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 their 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 a 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 product labelling within the EU/EEA. In Finland, the instructions for use of a test 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 and labelling for IVD devices intended for *self-testing* (at-home tests) must be provided in Finnish and Swedish.**

Reporting of adverse incidents

Healthcare professionals have a statutory obligation to notify Fimea and the manufacturer of the device or its representative, in practice the distributor

who supplied the device, of any adverse incidents related to medical devices. Layman users may also report problems with the devices to the authority or seller.

According to section 17 of the Act on Certain Medical Devices Specified in EU Directives, 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 or 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, on the other hand, is obliged to inform the authority of the adverse incidents and to investigate their underlying causes and to take the necessary corrective actions.

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 withdrawal of a defective product batch by the manufacturer or other urgent field safety notice. The authority concerned 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 self-tests.

Self-tests (at-home tests)

An IVD-device intended for self-testing is a test specifically intended by the manufacturer for layman use that has been proven to be safe and functional for this intended purpose.

An assessment by a notified body is always required for a self-test. If the product is intended for home use (it is an '*IVD device for self-testing*'), this is indicated in the instructions for use, in the declaration of conformity and in the separate certificate issued by a 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).

The marketing of self-tests is discussed in more detail below under section 'Marketing'.

The Finnish Institute for Health and Welfare (THL) has prepared more detailed instructions for self-testing for citizens (see the 'Further information' section below). The instructions explain, in layman's terms, what to do with negative or positive test results obtained from self-tests.

Importers and distributors of self-tests are strongly recommended to provide their customers with information about THL's additional instructions upon purchase of the self-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 information content of the instructions must be consistent with the information provided by the manufacturer. 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 form an integral part. The manufacturer is responsible for the whole of the medical device placed on the market.

Under section 17 of the Act on Certain Medical Devices Specified in EU Directives, the operator (for example, a distributor or importer) shall ensure that, when handing over a medical device to an end user, the device is in the condition in which the manufacturer 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 it had been 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, translation of user instructions, addition of the importer's contact information in connection with the product and other similar measures will be regulated through the IVD Regulation (see Regulation 2017/746, Article 16 for further details).

Other obligations of the distributor and importer

Provisions on the operator's obligations are set out on in section 17 of the Act on Certain Medical Devices Specified in EU Directives in particular. Under the Act, the operator is required, among other things, to comply with the manufacturer's information and instructions concerning the transport, storage, installation, maintenance and other handling of an *in vitro* diagnostic medical device.

Following the implementation of the IVD Regulation starting from 26 May 2022 at the latest, all distributors and importers dealing with SARS-CoV2 tests will also be subject to the requirements of Articles 13 and 14 of the IVD

Regulation. It is advisable to start the familiarisation with, and preparations for, the requirements well on time.

Marketing

Under section 11 of the Act on Certain Medical Devices Specified in EU Directives, section 10 of the Medical Devices Act and Article 7 of the IVD Regulation, the marketing* of medical devices may not convey an exaggerated or false image of the device or its effectiveness or use.

With regard to rapid Covid-19 tests, the correct use and user group of the test should be clearly indicated in the marketing.

In all 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 self-testing/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 self-tests and the verification of the results by means of a laboratory test as applicable must be taken into account in the marketing of self-tests. A negative self-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

Preconditions 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 laboratory 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).

Also, the use of self-tests in organised testing activities (e.g., event testing or self-testing required at the workplace) is, as a rule, subject to an operating licence. The Regional State Administrative Agency and the Finnish Institute for Health and Welfare advice in operating licence matters as needed.

The use of at-home tests in normal self-testing in which the person who purchased the test performs the tests on him- or herself or to a family member does not fall within the scope of the operating licence procedure.

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

Information on legislative changes: https://www.fimea.fi/web/en/-/laws-supplementing-eu-regulations-on-medical-devices-come-into-force

THL's instructions for citizens on at-home tests:
https://thl.fi/fi/web/infektiotaudit-ja-rokotukset/ajankohtaista/ajankohtaista-koronaviruksesta-covid-19/oireet-ja-hoito-koronavirus/koronavirustestit/koronaviruksen-kotitestit (FI)

https://thl.fi/en/web/infectious-diseases-and-vaccinations/what-s-new/coronavirus-covid-19-latest-updates/symptoms-and-treatment-coronavirus/coronavirus-tests/coronavirus-home-tests (EN)

About the requirements pertaining to testing activities:
https://avi.fi/en/services/businesses/licences-notices-and-applications/social-welfare-and-health-care/private-health-care/clinical-microbiology-laboratories

Operator and device register notifications related to medical devices (Fimea Administrative Regulation 2/2021)
https://finlex.fi/fi/viranomaiset/normi/558001/47297

Thank you for your cooperation,

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