tukes

Asta Koivisto

5 May 2020

Info session on the conditions for placing on the market

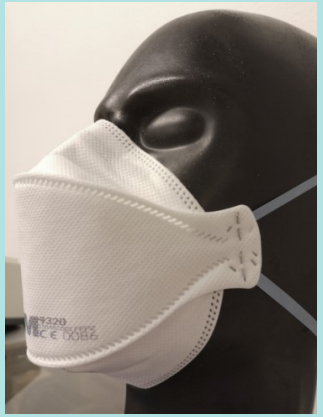
Finnish Safety and Chemicals Agency (Tukes)

Topics covered

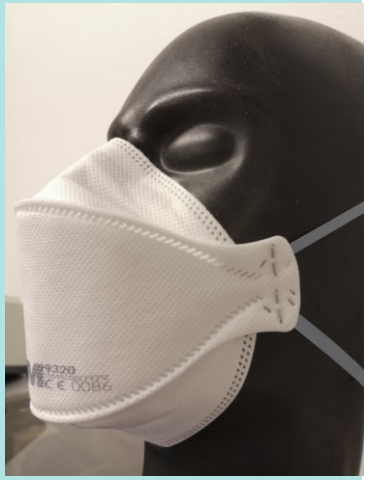
- Topics in the info session
  - For what purpose are the products sold?
    - Products intended for professional use
    - Products aimed at consumers
  - Legal requirements on products in brief
    - Respiratory protective equipment (Tukes and Ministry of Social Affairs and Health)
    - General consumer goods (Tukes)
  - How do I ensure that the documents I have are legitimate?
  - Useful links
- Questions?

The info session focuses solely on questions related to the products' placement on the market, not to the particulars of their use.

For what purpose are the products sold? Products intended for professional use

Ministry of Social Affairs and Health, Department for Work and Gender Equality (TTO)	**Respiratory protective equipment for professional use (FFP2 and FFP3, for example)** Purpose is to protect the wearer, in this case employees If a purpose of use is not specified, the PPE is deemed to be for professional use.	**Personal Protective Equipment Regulation (EU) 2016/425** Respiratory protective equipment are classified as category III PPE	**Things to note** The requirements were derogated on 31 March 2020. See the guideline on market placement by the Ministry of Social Affairs and Health.	
Finnish Medicines Agency Fimea	**surgical masks for health care personnel** Purpose is to protect persons other than the wearer, such as patients.	**Regulation (EU) 2017/745 on medical devices or Directive 93/42/EEC** Products must conform to the requirements of product Class I	**Things to note** The requirements were derogated on 1 April 2020. See the guideline on market placement by Fimea	

For what purpose are the products sold? Respiratory protective equipment intended for consumer use

Finnish Safety and Chemicals Agency (Tukes)	**Respiratory protective equipment for consumer use (FFP2 and FFP3, for example)** Purpose is to protect the wearer, in this case non-professional users The manufacturer must state that the respiratory protective device is intended to protect consumers.	**Personal Protective Equipment Regulation (EU) 2016/425** Respiratory protective equipment are classified as category III personal protective equipment (PPE)	**Things to note** For these products, the requirements for placing on the market have not been derogated. Products sold to consumers must conform to requirements on PPE in all respects.	

For what purpose are the products sold? General consumer goods intended for consumer use

Finnish Safety and Chemicals Agency (Tukes)	**Face masks for consumer use** Purpose is to reduce the spread of droplets on food, for example. Not marketed as possessing protective features	**Consumer Safety Act 920/2011 an Government Decree 613/2004 on information to be supplied in respect of consumer products and services.** Products must be suitable for their intended purpose and equipped with all necessary safety markings. General consumer products cannot have a CE marking.	**Things to note** **On marketing products**: If a product does not fulfil the requirements for PPE, consumers must not be given the false impression that the product in question would constitute a type of PPE. Products marketed to consumers as respiratory protective equipment must conform to requirements for PPE.	 These products may be highly similar in appearance to surgical masks. What is decisive is their intended use

Products surveilled by Tukes

Make sure you know your role

- Before taking action, make sure you know your role and the consequent legal obligations: https://tukes.fi/en/do-this/the-roles-of-the-actors
- Note: When importing products under your own brand, you are considered to be the manufacturer
- Parties involved in placing PPE on the market and their respective obligations (in Finnish)

Legal requirements on products
Respiratory protective equipment

- Must conform to the requirements of the PPE Regulation (EU)2016/425 – Requirements for PPE intended for consumer use have not been derogated.
- Respiratory protective equipment sold in Finland must include:
  - EU type-examination certificate (the type examination process is described in detailed on the Tukes website and in the PPE Regulation)
  - EU declaration of conformity (template in Annex IX of the PPE Regulation)
    - must be in Finnish and Swedish
    - must be supplied with the product or available on a website, with the link to the website in the user instructions
  - user instructions in Finnish and Swedish
  - CE marking and identification number of the relevant notified body on the PPE.
  - Manufacturer and product identifier on the PPE.
  - Technical documentation drawn up by the manufacturer (see Annex III of the PPE Regulation for more information). The manufacturer draws up technical documentation for the type examination.
- Note! The requirements are identical for all category III PPE. In the case of certain PPE intended for professional use as protection against the coronavirus, the requirements for placing on the market have been derogated.

How do I ensure that the documents I have are legitimate?

- EU type-examination certificate
  - Check that the product, including its model markings, can be connected to the certificate.
  - The Commission's Nando database lists notified bodies authorised to issue EU type-examination certificates
- EU declaration of conformity
  - Conforms to the template given in Annex IX of the PPE Regulation
  - Check that the product, including its model markings, can be connected to the EU declaration of conformity.
- If the manufacturer is unable to supply the documents listed above, the product may not be sold to consumers as a PPE (note the guidelines referred to in the first slide)
  - Similarly, if the CE marking is missing, the product cannot be sold to consumers as a PPE
  - Documents with titles such as 'Certificate of conformity' or 'Certificate of compliance' are not documents required by the PPE Regulation.
- Document audit services are provided by private service providers
- EFS's website with descriptions of what is wrong and links to known suspicious certificates

Requirements for products
General consumer goods

- General consumer goods must conform to the requirements of the Consumer Safety Act 920/2011
  - General consumer goods may not cause a hazard to consumers' health or property.
- General consumer products must not have a CE marking.
- If a product does not fulfil the requirements for PPE, consumers must not be given the false impression that the product in question would constitute PPE. If face masks or similar products are marketed to consumers as respiratory protective equipment, they must fulfil the requirements on PPE.
  - The product must have some other intended use, such as the protection of foodstuffs. Requirements for PPE may not be circumvented.

RESPIRATORY PROTECTIVE EQUIPMENT INTENDED FOR PROFESSIONAL USE

Pirje Lankinen
Ministry of Social Affairs and Health

Respiratory protective equipment intended for professional use

- must conform to the requirements of the PPE Regulation (EU) 2016/425

- technical documentation (manufacturer draws up, importer ensures that documentation exists)
- EU type-examination certificate (EC type-examination certificate)
- EU declaration of conformity
- user instructions in Finnish and Swedish
- CE marking and other labels

Commission Implementing Regulation (EU) 2020/402 making the exportation of certain products subject to the production of an export authorisation

- For the following products that protect against infectious materials:
  - protective spectacles, visors and face shields
  - respiratory protective devices (mouth-nose-protection equipment)
  - protective garments
  - gloves

- the authorisation procedure is in effect until 25 April 2020

- instructions for applying for export authorisation are available on the Ministry of Social Affairs and Health website (in Finnish)
  - Google: “STM export authorisations”
  - document to be updated

Commission Recommendation (EU) 2020/403 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat

- applies to manufacturers, importers and distributors of PPE
  → specifies the terms of sale of certain PPE

- **describes to what extent requirements on PPE intended for professional use as protection against the coronavirus have been derogated**
  → *the essential requirements of the PPE, i.e. the minimum level of protection required in the EU, must be met*

- Ministry of Social Affairs and Health list of derogated requirements
  - NOT a protection guidance!
  - NOT a full list of PPE suitable against the coronavirus!

Commission Recommendation (EU) 2020/403 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat

- in determining PPE that protect against the coronavirus, we have made use of
    - the list by the WHO
    - information supplied by certain EU countries on acceptable derogations
    - expertise of the Finnish Institute of Occupational Health (TTL)

- the list of PPE for which requirements can be derogated is available on the Ministry of Social Affairs and Health website
    - Google “STM guideline on the sale of PPE for coronavirus”
    - document to be updated

General (derogated) requirements for certain PPE used to protect against the coronavirus

- **must include a test report indicating that the essential requirements of the PPE Regulation (EU) 2016/425 are met→, i.e. protection level conforms to EU requirements**

- no EU type-examination certificate
- no EU declaration of conformity
- no CE marking
  - if the product has a CE marking, all requirements of the PPE Regulation (EU) 2016/425 must be met

- limited user instructions
- limited product markings

Three main points

- Ensure the intended use to which the product is manufactured/will be manufactured
- Ensure that the product's intended use is clearly stated
- Ensure that the product conforms to requirements

It is important that the product does not give a false sense of security to users

-

Useful links

- TTL website on PPE classification
- Memo on the Commission's interpretation
- List of standards offered by SFS
- Tukes' coronavirus webpage on RPE, incl. the following announcements:
  - Issues to take into account when selling respiratory protective equipment
  - Self-made masks do not protect the user from coronavirus
- Fimea webpage on COVID-19
- Tyosuojelu.fi on PPE intended for professional use
- SGS factsheet on PPE

Questions?

Please leave us feedback at: https://webropol.com/s/infotunti

tukes