Fast Tracking or CE Marking

Similarities and differences in personal protective equipment inspections

This table describes the similarities and differences between fast tracking without CE marking and traditional CE marking. Personal protective equipment (PPE) comes in numerous forms, and we deal with PPE that is classed in various ways based on established health and safety requirements. In the table below, Class II and Class III products are described collectively *(anything that protects against risks more serious than trivial risks such as those that may result in e.g. abrasions, bruises, chafing).* Importers and manufacturers constitute potential clients. **Fast track without CE marking is the alternative to be chosen by non-business activities, e.g. authorities, regions and municipalities.**

	Fast tracking without CE marking	**Traditional CE marking**
Manufacturing	Technical documentation* must be produced for the manufactured or imported product. If complete information is not available, especially when importing (eg labeling, instructions for use in languages that the owner needs to master), a solution can be found together with the Swedish Work Environment Authority.	Likewise. Technical documentation* must be produced for the manufactured product.
Testing	Processes in the testing standards have been amended to speed up the time required for testing, without adversely affecting the health and safety requirements during the validity period. RISE specifies how many products are needed for testing.	Carried out according to applicable standards and by an accredited laboratory.
Manufacturing inspection	Not carried out.	Carried out for Class III products.
Evaluation for type-examination certificate/ Certification	Not carried out, this is done through the Swedish Work Environment Authority.	Testing and technical documentation* evaluated. Evaluation results in a type-examination certificate.
Swedish Work Environment Authority	The licence issuing agency. If YES, the manufacturer must mark the product with 'Covid-19', if it is not already done. Authorities, regions and municipalities, which do not have commercial activities, must choose this route.	Not involved. It is incumbent on the manufacturer to label the product with the CE mark.
Period of validity	Until 31/12/2021	Valid for 5 years. Many customers are now opting for fast tracking and are also selecting this option for future sales.
Entities requiring PPE	Carry out a risk assessment of how the product is to be used according to the instructions for use and product sheet.	Instructions for use and product sheet made available in order to carry out a risk assessment.

*Technical documentation. This refers to **risk analyses** with product action plans, **product specifications, drawings, product sheets, instructions for use and marking.**