An Expert Advice Sheet

hutchison international

Quality & Compliance

Understanding the system of Standards and CE Marks.

ISO13485 certified supply chain management

As the lockdown eases many businesses are faced with the question how do I keep my employees safe? Whether that is finding ways to maintain social distancing or providing PPE, quality and complaince is something you need to be aware of.

This guide has been complied to help you understand the system of Standards and CE Marks. If you are looking to purchase PPE please see our guide to purchasing compliant and certified PPE.

Why does it matter?

In a global marketplace, checks and balances need to be in place. Otherwise, it would be difficult to maintain consistency and quality across industries and nations. National, European and International standards help to keep a level playing field, reduce waste and, arguably most important in our current environment, protect the consumer through the use of licensed marks to identify conformity to standards.

License and Standards marks

BS EN ISO – all refer to organisations which initiate, publish and maintain standards.

National standards specify the requirements for application in the particular country. British Standard – BS denotes Britain's National Standards which are controlled by the British Standards Institute (BSI). EN denotes a Standard which is adopted by the European community and is controlled by the European Committee for Standardisation (CEN). ISO denotes a worldwide standard issued by the International Organisation for Standardisation.

European standards are aimed at facilitating commerce between the countries of the European community. Once a European Standard has been agreed it supersedes any existing national standard and becomes the new national standard. These Standards are prefixed with EN. Once an International Standard has been adopted as a European Standard it supersedes the existing European standard. These Standards are prefixed with EN ISO.

In the European market a CE Mark represents a manufacturer's declaration that a product:

- fulfills the requirements of relevant European product directives.
- meets all the requirements of the relevant recognised European harmonised performance and safety standards.
- is fit for its purpose and will not endanger lives or property.

A CE Mark does not show evidence of third-party testing but is an indication that appropriate technical documentation supporting the use of the mark is available and can be provided. However, PPE Categories II & III do have requirements for independent testing* before the CE Mark can legally be applied.

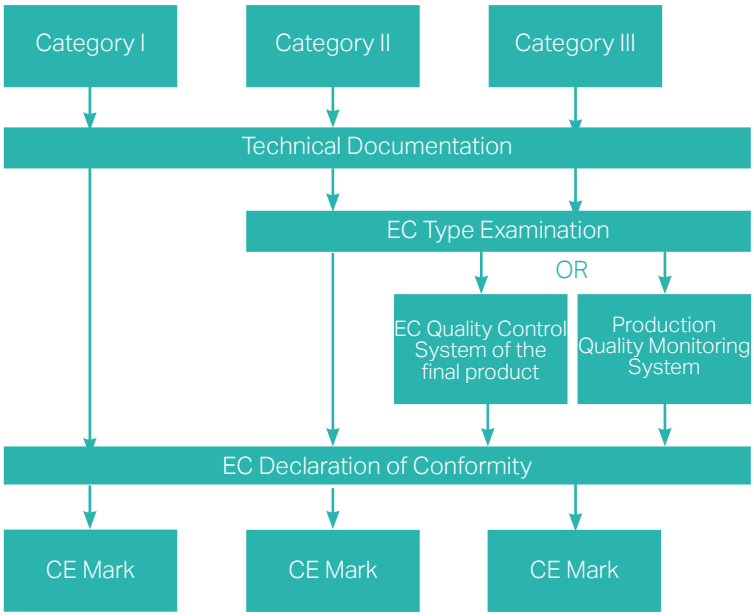
CE Marks and Personal Protective Equipment

In Europe, Personal protective equipment or PPE is either a device, clothing, glove or appliance, worn or held by a person at work, which is designed to protect that person against one or more health and/or safety hazards.

There are three categories of PPE:

1. Category I (Simple Design) - for use against minimal or minor risks.
2. Catergory II (Intermediate Design) - for use against intermediate or reversible risks.
3. Catergory III (Complex Design) - for use against mortal or irreversible risks.

Each categories route to conformity is shown below:



PPE meeting the basic requirements of the EU Regulation 2016/425** is considered safe to be sold in Europe, and can be recognised as such by the CE Mark and other relevant information.

At Hutchison we continually strive to conform to the highest and most current internationally recognised standards. We do this because it helps us to reduce waste and maintain the highest quality, but most importantly it means our customers can be confident in the products we supply. In todays climate that means they can trust the PPE we supply is fit for purpose and will not endanger lives.

'Big business results, small business values.

We are Hutchison.'

* These tests are performed by a Notified Body. An Notified Body is a testing and certification body that is authorised to test, monitor and certify products, machines and equipment. In the UK the Notified Bodys are appointed and overseen by the Medicines and Healthcare products Regulatory Agency.
** The previous PPE Directive (89/686/EEC) was replaced by a new EU Regulation 2016/425 on the 21/04/18. EC type-examination certificates issued under Directive 89/686/EEC shall remain valid until 21/04/23 unless they expire before that date.