How to get safety footwear marked CE
The European Union and the United States of America are the world’s largest safety footwear markets. Both have comprehensive legislation covering the workplace environment and performance requirements for safety footwear. Although other parts of the world have different legislation, the industrial hazards are generally very similar. Regardless of country, protective and safety footwear often incorporates similar features, such as safety toecaps and under-foot protection. More specialist footwear has been developed to protect against other physical risks, such as cutting by chainsaws, or environmental hazards associated with chemicals, heat and electricity.

The European Personal Protective Equipment (PPE) Directive 89/686/EEC defines PPE as clothing and equipment “designed to be worn or held by an individual for protection against one or more health and safety hazards”.

Since the Directive became part of European law in 1995, suppliers of PPE in the European market have had to follow the appropriate approval procedure to CE mark their products. SATRA is one of the leading Notified Bodies for the CE marking of PPE intended for the European market and has been influential in the development of PPE-related test methods and safety standards. SATRA’s testing and certification services cover most areas of PPE – from head protection to safety footwear, and nearly everything in between.

The Directive covers a range of products, which it divides into three categories. These are based on the risk, consequences and severity of injury likely to occur to someone not wearing adequate PPE. The procedures for demonstrating compliance and the involvement of a Notified Body differ for each category.

‘Simple’ design PPE covers products that are claimed to provide protection against minimal risks, with effects that are gradual and can be safely identified by the user in good time. Products in this category (commonly called Category 1), washing-up gloves for example, are listed in the Directive. Category 1 PPE can be ‘self-certified’ by the manufacturer or European importer without the need for third-party verification. The involvement of a Notified Body is not required. However, an enforcement authority would expect to be able to examine a technical dossier backed up by appropriate test reports. Therefore, it is recommended that records of some testing carried out by an independent test centre be kept, to provide documentary evidence to support any claims made about the product.

‘Complex’ design PPE (Category 3) covers products claimed to provide protection against risks of mortal danger, or dangers that may seriously and irreversibly harm the health of the user. Again, a list of such products is detailed in the Directive. These products must be certified by a Notified Body and are subject to initial type examination and continual production checks. This category includes footwear for fire fighters, for protection against molten metal in foundries or for high voltage protection.

All other products (neither simple nor complex) fall into a third category often called ‘Intermediate’ design or Category 2. These are products claimed to provide protection against risks of severe injury. A Notified Body must certify initial examples of such products and any associated documentation. Most safety footwear falls into this category.

European harmonised standards
As the Directive is a piece of general legislation, it includes health and safety requirements that must be taken into account for all types of PPE. It does not, however, detail how particular types of product should be tested. To support the Directive, the European Union Commission has mandated the development of various product safety standards through the European standards agency CEN (Comité Européen de Normalisation). CEN has convened a technical committee, referenced CEN/TC 161, to develop a series of harmonised European standards for use in testing and certification of foot and leg protection.

These European standards describe in detail how a particular type of product should be tested and what performance is required to achieve a satisfactory pass. The tests developed...
EN ISO 20345/6/7 MARKING CODES

- EN ISO 20345 SB – Toe protection tested with 200J impact and 15kN compression force.
- EN ISO 20346 PB – Toe protection tested with 100J impact and 10kN compression force.
- EN ISO 20347 OB – No toe protection against mechanical hazards provided but must provide protection to one or more of the categories P, C, A, E, CI, AN, WR or HI as described below.

CLASSIFICATIONS OF FOOTWEAR

Class I – Footwear made from leather and other materials, excluding all-rubber or all-polymeric footwear.
Class II – All-rubber (entirely vulcanised) or all-polymeric (entirely moulded) footwear.
Hybrid – Class II footwear incorporating another material that extends the upper.

- HRO – Heat resistant outsole compound tested at 300°C
- P – Penetration resistant outsole tested at 1100 newtons
- A – Electrical resistance between foot and ground of between 0.1 and 1000 mega ohms
- C – Electrical resistance between foot and ground of less than 0.1 mega ohms
- AN – Ankle protection – mean transmitted force <10kN when tested at 10J
- CR – Cut resistant upper – cut index >2.5
- CI – Insulation against the cold – temperature drop less than 10°C when tested at -17°C
- HI – Insulation against heat – temperature increase less than 22°C when tested at 150°C
- E – Energy absorption of the seat region tested at 20 joules
- WRU – Water resistant upper leather
- WR – Water resistant footwear
- M – Metatarsal protection – tested with 100J impact
- FO – Oil-resistant outsole (applies to EN ISO 20347 only)

The following short codes are for commonly used combinations:

- S1 – Footwear made from leather and other materials excluding all-rubber or all-polymeric footwear + closed seat region + SB + A + E + FO
  - S2 – S1 + WRU
  - S3 – S2 + P + cleated outsoles
  - S4 – All-rubber (entirely vulcanised) or all-polymeric (entirely moulded) footwear + SB + A + E
  - S5 – S4 + P + cleated outsoles.
- P1 – Upper footwear made from leather and other materials excluding all-rubber or all-polymeric footwear + closed seat region + PB + A + E + FO
  - P2 – P1 + WRU
  - P3 – P2 + P + cleated outsoles
  - P4 – All-rubber (entirely vulcanised) or all-polymeric (entirely moulded) footwear + PB + A + E
  - P5 – P4 + P + cleated outsoles.
- O1 – Footwear made from leather and other materials excluding all-rubber or all-polymeric footwear + closed seat + A + E + FO
  - O2 – O1 + WRU
  - O3 – O2 + P + cleated outsoles
  - O4 – All-rubber (entirely vulcanised) or all-polymeric (entirely moulded) footwear OB + A + E
  - O5 – O4 + P + cleated outsoles.
- SRA – Slip resistance on ceramic tile floor with SLS*
- SRB – Slip resistance on steel floor with glycerol
- SRC – Slip resistance on ceramic tile floor with SLS* and on steel floor with glycerol.

*SLS = Sodium lauryl sulphate solution
Governments and notified to the European Commission on the basis of their ability to carry out the examinations and tests required for marking of PPE. They must be independent, impartial and have a high level of professional indemnity insurance. There are currently around 110 Notified Bodies throughout Europe – 105 in EU Member States and 5 in EFTA countries (all in Switzerland and Norway). These are all subject to routine surveillance at regular intervals. It is possible to identify which Notified Body has certified a product as the body’s name, address and unique number must be displayed on the accompanying user information. Representatives from the Notified Bodies meet regularly to ensure that standards and legislation are applied uniformly across Europe. These groups are usually referred to as Vertical and Horizontal Groups.

**EC type-examination**

It is mandatory for suppliers of Complex and Intermediate design PPE to have initial examples of their products assessed by a European Notified Body such as SATRA. This process, called EC type-examination, checks the design and documentation of a prototype or initial example of an item of PPE to ensure it is fit for its intended use and satisfies the BHSR of the Directive. This assessment is based on the claims made about the product in the user information and is achieved by:

1. Examining the design documentation (referred to as the technical file) to ensure first that the product satisfies all the relevant sections from the list of basic health and safety requirements given in Annex II of the PPE Directive; and secondly, that the product is adequately described through the use of diagrams and lists giving the source of all materials.

2. Carrying out a series of tests and examinations on the products to ensure they meet the claimed performance levels. This may be carried out to harmonised European standards or, if required, the manufacturer and Notified Body can use an agreed technical specification. The test reports are then added to the technical file. If EC type-examination is successful, a certificate is issued by the Notified Body to prove the item’s conformity. For intermediate products, this is effectively the end of the Notified Body’s involvement and the certificate holder becomes responsible for ensuring that subsequent production remains the same as the model examined by the Notified Body.

**Production checks**

In addition to initial type examination of the prototype model, Complex design PPE is subject to checks by a Notified Body to ensure that production versions of the item continue to comply with the sample that was approved by the EC type examination. It should be noted, however, that the Notified Body that carries out the Article 11 assessment need not be the same as the Notified Body that carried out the original type approval. The manufacturer or authorised representative can choose one of two methods for the Notified Body to use when checking the conformity of ongoing production:

- **Article 11A (Product Monitoring)** – This involves the Notified Body selecting and removing random samples of manufactured items of PPE which are then tested by methods such as those used in the original EC type-examination to ensure continuing compliance.

- **Article 11B (Quality System Monitoring)** – The Notified Body visits the manufacturing site to check that the quality systems used by the
manufacturer are capable of enabling consistent production of the certified product. SATRA uses quality management system auditors registered with the International Register of Certified Auditors (IRCA) for this work.

Both Article 11A and 11B assessments are carried out on a regular basis while that item of PPE remains in production.

**Step by step guide to CE marking with SATRA**

1. It is essential that manufacturers have access to copies of the standards associated with their particular products and familiarise themselves with the requirements. If they don’t, it is more difficult to manufacture products that are likely to be immediately suitable. We recommend you obtain a copy of the National Legislation that enacts the European PPE Directive, as this is the legislation that controls the placing of PPE on the European Market. Copies of documents can be purchased from SATRA (email testmethods@satra.com).

2. We recommend that products are designed taking into account the requirements of the product standard(s). This sounds obvious, but we still see many instances where a product has been made first and then legislative requirements considered later. With many standards there are a number of optional properties, so it is important at this stage to decide what category of protection is required. Manufacturers may also wish to commission some limited experimental tests to identify any potential design problems.

3. Where the involvement of a Notified Body is required, the manufacturer or authorised representative needs to make a formal application for EC type-examination. Amongst other things, this will confirm the name of the organisation the certificate should be issued to, the product identifiers and the product test specification. Ideally the application form should be accompanied by the technical file and product samples. A basic template of a technical file is available on request for member companies.

4. The Notified Body assessor will need to confirm that appropriate tests have been carried out. SATRA has some of the most extensive testing facilities in the world and many clients also require us to test their products.

5. In addition to performance testing against the specific product standard, EC type-examination against the PPE Directive also requires an assessment of innocuousness – confirmation that the product will not harm those who come into contact with it, including the wearer. At its simplest this may be a check that there are no sharp edges or points.

6. In addition to confirmation of the product’s physical attributes, EC type-examination also includes assessment of a technical dossier, called the ‘technical file’. This should include:

   - Name and address of the manufacturer.
   - EU authorised representative (if relevant).
   - Product specifications (drawings, photographs and construction details).
   - Raw material specifications (including the full postal address of the supplier).
   - Quality control and test facilities used at the manufacturing plant.
   - Product marking (artwork of the information to be affixed to the product).
   - Copy of user information sheet.
   - Details of how the product complies with Annex II of EC Directive 89/686.
   - Details of how the certificate holder intends to comply with Article 11 of EC Directive 89/686*.
   - Test reports (especially those being used to support the EC type-examination). [* Complex design products only]

7. SATRA will assess the technical file and if necessary, request any additional information needed to satisfy the minimum requirements. When the file is considered to be satisfactory, an EC type-examination certificate is produced.

European legislation also covers a number of restricted chemical substances, therefore SATRA also needs to confirm the product does not contain any of these before a certificate can be issued.

Restricted substance legislation includes:

- EC Directive 2002/61/EC – Azo Colourants (Dyes)
- EC Directive 1999/51/EC – Pentachlorophenol (PCP)

Products also need to be assessed against EN ISO 13688:2013 General requirements for clothing; also see Annex 17 of REACh.

Current guidance is understood to be that the CE mark signifies compliance with all relevant legislation. Therefore compliance with Azo Dye, PCP or Nickel directives (via national legislation) is mandatory.

Resistance to radiant heat is an important property for some types of safety footwear.
8. SATRA returns the technical file (but keeps a copy) together with the EC type-examination certificate. These should be kept in a safe place (ideally in a European office) as the relevant European enforcement authorities may need to see them as part of any investigations if there is a problem in the future.

9. The certificate holder must draw up an EC Declaration of Conformity; a written commitment to manufacture the products in exactly the same way as the model that was type approved. Any changes to subsequent production should be discussed with and reviewed by the Notified Body, or the certificate may no longer be valid.

10. Products can now be manufactured and placed on the European market provided that:
- The design remains unchanged.
- The products are marked in accordance with the technical file.
- The products are supplied with user information as detailed in the technical file.

11. In the case of complex design products, maintain ongoing compliance in accordance with one of the two Article 11 routes.

It is important to remember that the EC type examination certificate remains the property of the Notified Body. Although we cannot prevent organisations supplying product to the market, we can withdraw the certificate if we have sufficient grounds to consider it being abused in some way.

Notified Bodies such as SATRA carry out a crucial role in assessing PPE products – facilitating European trade by ensuring safety and consistency of application through harmonised European standards and the PPE Directive requirements. This provides consumers with a measure of confidence that products have been assessed against recognised standards or other specifications by an independent third party, which is itself assessed for competence. It is important to remember that, with the exception of complex category products, where the same Notified Body has been nominated to carry out additional responsibilities to periodically assess ongoing production, a Notified Body does not see the vast majority of PPE produced after initial type examination. Responsibility for ensuring consistent production in accordance with the initial type examination lies with the certificate holder.

**EN ISO 20345/6/7 Categories of protection**

The current European footwear standards are:
- Safety footwear: EN ISO 20345:2011
- Occupational footwear: EN ISO 20347:2012

These all refer to EN ISO 20344 for details of the test procedure.

The three main footwear product standards (EN ISO 20345/6/7) include a range of optional tests each with an associated marking code; see box. The number of samples required to carry out testing to these standards depends on a number of factors, as test specimens must be cut from the upper/outsole/insole area. Factors affecting how many samples are required include the number of upper materials present and the shape and size of the various upper panels. However, provided the design of the upper is relatively simple with only one upper material and a limited number of seams, the following samples should be sufficient:
- 4 pairs of footwear in the smallest size from the range to be produced
- 4 pairs of footwear in the largest size from the range to be produced
- 4 pairs of footwear of a size from the middle of the size range
- A4 cuttings of upper and lining materials.

Impact tests are carried out at 200J and 100J energy (EN ISO 20345 and EN ISO 20346 respectively)

- Forestry footwear: EN ISO 17249:2013
- Footwear against chemicals: EN 13832:2006 Parts 1-3
- Firefighters’ footwear: EN 15090:2012
- Footwear against molten metal: EN 20349:2010
- Electrically insulating footwear: EN 50321:2000
- Footwear for motorcyclists: EN 13634:2015

The trough test from EN ISO 20344 assesses water resistance – marking code W R
for the various standards are designed to assess products against the requirements of the PPE Directive for the risks of the particular activity for which they are to be used. The European Commission reviews these standards and, if they are found suitable, they become officially harmonised throughout Europe, and receive a ‘presumption of conformity’ for the parts of the Directive detailed in Annex ZA of each standard. The publication of the standard is also mentioned in the official journal of the EU. Hence, when starting the CE marking process, it is necessary to review Annex ZA of any harmonised standard to be used, to ensure that all relevant clauses of the Directive are addressed.

Harmonised standards are not the only means of demonstrating compliance with the PPE Directive. A manufacturer can use any technical specification as long as it can be shown to satisfy the relevant basic health and safety requirements (BHSR) of the PPE Directive. However, if a harmonised standard is available for the particular product being examined, there should be a sound technical argument if it is not used. In certain areas, such as niche or leading edge products, there may still be no harmonised standards available. In such cases a technical specification detailing how compliance is to be demonstrated must be produced and used. SATRA has certified a number of products where harmonised standards or satisfactory national standards do not exist and has produced a series of SATRA specifications (referred to as ‘M’ Documents) to cover them. Typically the tests necessary to certify an item of PPE cover all of the following four main categories:

1. Innocuousness:
   This usually includes some quantitative tests, such as measuring the quantity of trace toxic substances in the product or its raw materials. It may also involve a subjective assessment for any parts of the product that may cause injury, such as sharp edges.

2. Ergonomics:
   Usually a small-scale practical wear trial which involves the wearer carrying out a range of movements typical of normal use and reporting any restrictions or discomfort caused by the PPE.

3. Protective coverage:
   Particularly important for products such as impact protectors. Minimum dimensions are specified, which are usually dependent on the size of the intended wearers, and the area of coverage is often checked against a standard template.

4. Protective qualities:
   A range of physical laboratory tests to mimic accident scenarios, such as measurement of resistance to impact, penetration, cutting, burning and the flow of electricity.

During the development of CEN standards (ENs), individual EU member states are prohibited from working on their own standards (this process is formally referred to as ‘standstill’). This ensures that all new standards produced for products covered by the PPE Directive do not differ significantly between EU member states. For instance, safety footwear designed and sold in Germany should be tested to the same standard as a similar product designed in France or the UK.

CEN standards are achieving widespread acceptance worldwide. A number of countries outside Europe have taken advantage of the progress being made under the PPE Directive either by using the relevant ENs or modifying them slightly to meet their own requirements. Many European standards also form the basis of standards produced by the International Standards Organisation (ISO). Others are developed jointly between CEN and ISO under the ‘Vienna Agreement’, which is intended to help reduce duplication of effort. The current safety footwear standards EN ISO 20344 through to EN ISO 20347 are a good example of this.

**The role of Notified Bodies**

Notified Bodies, such as SATRA, are Europe-based organisations that have been appointed by Member State