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# Conformance

CE MARKING & PRODUCT SAFETY

## How Conformance will assist you in CE marking your products

### 1. The CE-marking process

#### 1.1. There is a series of steps that manufacturers must follow.

The term “manufacturer” is defined quite widely and can include those importing products made outside Europe and persons making items for their own use.

Own-branding an item normally makes you the 'manufacturer' for the purpose of CE-marking.

These steps are:

- o Identify which CE-marking directive(s) apply
- o Identify appropriate standards
- o Assess the product against those standards
- o Rectify any non-compliances
- o Issue a Declaration of Conformity
- o Compile a Technical File
- o Affix the CE mark

#### 1.2. There is a further step, outside the scope of Conformance’s involvement: For series-produced items, ensure that you have adequate manufacturing processes to ensure that every item produced complies.

### 2. How Conformance helps you

2.1. Identifying which directives apply – we will analyse your equipment/its documentation and identify which directives are relevant. Most commonly, there is a main safety-related directive and additional environmental directives.

2.2. In the majority of cases, the process of CE marking is one of self-certification with the manufacturer affixing the CE logo on a product without the intervention of any third party provided that the requirements of the applicable directives are met. A brief overview of these steps is described in this procedure.

Conformance Ltd. will assist you with CE marking process, advise you on your legal obligations and perform an evaluation of the equipment together with its associated documentation.

Note that this procedure does not cover lifting accessories etc. or certain items of machinery (as listed in annex IV of the Machinery Directive) that cannot be self-certified.

### 3. **Applicable directives**

We will determine which of the following CE marking directives apply to your equipment:

- The **Machinery Directive** 2006/42/EC requires all equipment, with powered moving parts, to be properly designed to reduce hazards to acceptable levels; to provide specified, supporting documentation; and be supplied with adequate instructions.
- The **Low Voltage Directive** 2014/35/EU requires electrical equipment to be safe, having particular regard to protection against electric shock, and prevention of fire. It applies to most mains powered equipment.
- Most electrical equipment must comply with The **Electromagnetic Compatibility (EMC) Directive** 2014/30/EU. This requires apparatus to emit only limited amounts of electrical noise and to operate satisfactorily under likely conditions of electrical interference.
- Where the equipment contains intentional radio transmitters or receivers, the **Radio Equipment Directive** 2014/53/EU applies in place of the LVD and EMC directives.
- The **Restriction of Hazardous Substances Directive (RoHS2)** 2011/65/EC which prevents new electronic and electrical equipment from being placed on the market in the EU if they contain certain hazardous substances above stated levels. This Directive outlaws the use of certain banned substances such as lead, mercury and some halogenated flame retardants in electrical and electronic products.
- The **Waste Electrical and Electronic Equipment Directive (WEEE)** 2012/19/EU. The requirements of this Directive are that all manufacturers of electrical and electronic products must make arrangements to ensure that their products do not enter the landfill waste stream at the end of their life.

The following Directives may also apply:

- The **ATEX Directive** 2014/34/EU. This requires equipment and protective systems intended for explosive atmospheres to be designed and manufactured to minimize the occurrence and limit the severity of accidental explosions
- The **Noise Emission of Outdoor Equipment Directive** 2000/14/EC. This CE marking directive applies to 57 specified types of apparatus, the majority of which are mobile equipment designed for outdoor use. The Directive applies irrespective of power source

- **Pressure Equipment Directive** 2014/68/EU. This Directive applies to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure greater than 0.5 bar gauge including vessels, piping, safety accessories and pressure accessories.
- **The Ecodesign Directive** 2009/125/EC aims to limit the energy consumption of appliances during the equipment's manufacture, disposal and operational life. The Implementing Measures (IMs) of this directive can cover the manufacture, use and disposal of equipment. Currently, IMs focus only on use and only affects certain items of equipment.
- **Non-Road Mobile Machinery Directive** 97/68/EC. (Amended as 2012/46/EU) addresses the exhaust emissions from most equipment with internal combustion engines.
- **The Registration, Evaluation, Authorisation and Restriction of Hazardous Chemicals Regulation (REACH)** EC/1907/2006 is concerned with the safety of chemical substances placed on the EU market. The REACH Directive controls the way in which chemical substances placed on the market are evaluated for safety and how information on them is presented and published. It is generally only an issue for manufacturers who are importing novel substances or are using existing substances for novel applications.

#### 4. **Scope of our services for the purposes of CE Marking your equipment**

Having determined the applicable directives, the next steps are as follows:

- Search for appropriate standards which define the design measures recommended to meet the essential requirements of each directive;
- Assess the product for compliance with the directives and standards and note any non-compliances;
- Rectify any items of non-compliance.
- Compile a Technical File to provide evidence of compliance with the directives and standards.
- Issue a Declaration of Conformity for the product. (For partly completed machinery a Declaration of Incorporation is to be issued).

For the items listed above, Conformance will assist you by means of the following:

##### 4.1. **Standards search**

- We commence with a search for applicable standards, including those that are harmonised to the applicable Directives, which represent current best practice for the equipment. (Note that our quotation does not include supplying you with copies of the standards; however, we will provide a list of applicable standards as part of our report).

#### 4.2. **Assessment to the essential requirements of the applicable safety directive(s)**

- We can verify compliance with the requirements of the standards by means of standards-based checklists and a review of the equipment and its documentation. (An assessment to drawings and design information is possible for simpler products if no sample is available). We will determine the areas of non-compliance and submit these to you in a report. Alternatively, you may perform your own assessment by using our checklists. The checklists come with guidance documents that help you to understand the process and explain how to use the checklists effectively. We can provide assistance if required.
- Once all the non-compliance issues have been addressed, the checklists form a record of the compliance of the product at the time it was assessed and are to be included within to the Technical File for the product.
- If we determine that the equipment is Partly Completed Machinery, we will identify any non-compliances and give advice on the installation instructions on how they are to be rectified.
- The equipment may rely both on physical measures and on control system functions to maintain the safety of operators and others. (Examples of physical safety measures are guards and warning notices; examples of safety related control functions (SRCFs) are emergency stops and guard interlocks).
- SRCFs must ensure that the equipment functions in a safely manner under normal operating conditions and in the event of certain faults. The ability to correctly perform these functions is known as 'functional safety'.
- Control systems must be designed and constructed to ensure an adequate level of safety is provided. Analysis of such systems can be complex, particularly where there are significant numbers of SRCFs or where programmable systems are used. Our preliminary review will confirm whether or not the correct process for identifying, specifying and implementing the SRCFs has been followed. If required, we can provide assistance in ensuring that the documentation for your SRCFs meets the requirements of the applicable standards.

#### 4.3. **Assessment to the EMC Directive** (*This is only applicable to equipment with electrical power or controls*).

- Manufacturers are to complete an EMC assessment to confirm that their equipment will meet the requirements of this directive, with that assessment then being retained in the Technical File.
- It is often difficult to identify whether EMC testing will be required without first examining the equipment. In most cases, therefore, we start by reviewing the product and available EMC performance information to determine whether we can justify a claim of compliance on the basis of any work that has already been completed. (Clients may already have some EMC test information but this will need to be looked at in detail to enable us to decide whether it is sufficient). If it is possible to justify a claim of compliance without the need for additional testing, our EMC report will fulfil the Directive's requirement for an EMC assessment. (Note that Conformance Ltd does not have EMC test facilities but we can arrange for the tests if so required).

#### 4.4. **Assessment to the Environmental Directives**

- **The RoHS Directive**
- **The Ecodesign Directive**
- **The WEEE Directive**
- **The REACH Directive**

For these directives, we identify whether your product is within the scope of the directives. If it is, we will provide you with guidance on what your obligations are under each of the applicable directives. If your product is not in scope, we will provide a documented reason for why it is excluded which you can then include in your Technical File.

#### 4.5. **Declaration of Conformity and Technical File**

- When the product is CE marked, the manufacturer (or the responsible vendor) signs a Declaration of Conformity that includes identifying the product; who is responsible for CE marking it; and which standards have been applied.
- Once we have completed the product review and outlined how the machinery can be made to comply with the Directives, we will provide you with a draft Declaration of Conformity and guidance on the content of the Technical File. Normally, the manufacturer completes the Technical File since they have full knowledge of all the necessary information to show that the product is correctly designed and specified for its purpose. We will provide you with copies of our assessment checklists and details of the other information which is to be included in the file.