GUIDE FOR SELLING ELECTRICAL EQUIPMENT ON THE EUROPEAN MARKET

Revision 2

Contents

1. Purpose of this Guide

In our daily work as certification staff and staff of an accredited testing laboratory, we encounter frequent **questions and demands of manufacturers or importers of electrical and electronic equipment (hereinafter EEE) who want to place them on the EU market.** Most enquirers do not have the ambition to pay too much attention to the relevant provisions and choose, in their opinion, the easiest way: they contact a certification body and apply for a "CE certificate". They mostly think that, by receiving such certificate, their duties will end and all responsibility will then lie on the certificate issuer.

Unfortunately, European provisions related to the requirements for EEE are not simple and compact (ie: they appear in many different documents, and there is no simple 'list of requirements' applicable to all types of EEE). That is why **this guide was created** for individuals and companies with little orientation in the relevant EU legislation, **to offer** them **basic hints how to meet all EU requirements and not to forget anything important.**

1.1. Some technical remarks

1. The text of this Guide uses four fonts. In addition to the basic type (which you are currently reading), **the most important summary information is written in bold** – this should make it easier to find your way around the text.
2. Italics are used for quotations, in the documents names, or to highlight certain terms, usually when they are first used.
3. Notes and examples are written in smaller size and lighter colour. These help to illustrate the text, but are not crucial for understanding of the basic meaning. So you can easily skip them during the first reading.

   Here is the first of them:

   Electrical equipment is defined as "*any equipment used for the production, conversion, transmission, distribution or use of electricity, such as electrical machinery, apparatus, appliances, protective equipment and accessories for the distribution system.*"

4. This Guide is intended for basic orientation only. It cannot replace many dozens of pages of provisions, standards and other documents. Therefore, if we omit the remarks, it is relatively brief. However, it should provide sufficient links to these documents or their lists.
5. The knowledge of readers is different and the requirements for individual types of EEE are also different. Therefore, pay some attention to its content and structure. You don't have to read what you know or what does not apply to you.
6. The language of this guide should be easy-to-understand to almost everyone. If you do not understand something, **at the end you will find explanations of the most important terms, abbreviations and also links to other more detailed documents.**

2. General provisions for products on the EU market

There are hundreds of thousands of products sold on the EU market. The provisions setting out the requirements are very different – both in terms of the extent of these requirements, and their coordination within the EU.

In this Guide, the EU market means the *European Single Market*, which includes all EU Member States and certain other associated countries. Four countries that are also members of the European Free Trade Association have almost full access to the EU market: Iceland, Liechtenstein, Norway and Switzerland. Georgia, Moldova and Ukraine have more limited access.

However, the conditions for marketing products on the EU market also apply to some extent in some other countries, especially those that are negotiating to join the EU (e.g. some countries of former Yugoslavia, or Turkey).

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In addition to the many product groups where requirements are regulated at the EU level, there are large product groups where requirements are set at national level (and may vary from one EU country to another),

as well as procedures for demonstrating compliance (EU terminology uses the term "demonstration of conformity with the requirements").

Elsewhere, the requirements are set by industry branches – by big manufacturers or their unions – and in some cases there are no specific requirements.

1. Examples of products regulated at national levels: most of foodstuffs, agricultural products, drinking water, etc.

   A large share of regulation by industry branch is, for example, in the automotive industry. Large corporations usually have their own systems of company standards, which are not fully compatible with each other, but are also respected by national authorities approving launch of their vehicles into service.

   Minimum degree of regulation applies, for example, to simple tools, handicrafts or art objects.

2. Why are the provisions so complex and inconsistent? – Well, as the market is very complex. There are millions of products, hundreds of thousands of operators (manufacturers, dealers, distributors), over two dozen Member States. The particular interests of producers, trade unions, public authorities, consumer organizations often vary widely, and it is not easy to find compromises. The process of simplifying and unifying provisions is progressing – but slowly.

However, **there is a minimum regulation for all products. It is covered by European Directive 2001/95/EC *on general product safety*.** In short, it states that all products (even used and modified ones) offered on the market "*under normal or reasonably foreseeable conditions of use… present no or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons*".

The product should therefore not be unnecessarily sharp (ie: where it is not supposed to be – a kitchen mixer may, of course, have sharp blades, but you should not cut yourself on an edge of the top protective cover), hot (eg: the handle of an iron), poisonous, etc. Similarly, a desk lamp should not spark or hit you by electricity.

This general safety principle applies always – even if not explicitly stated in special provisions. This also includes EEE.

The text of the general safety directive – and of all the EU legislation listed below – is freely available on EURlex website, as amended (ie: in its currently valid version).

1. We are going to quote the titles of provisions in an easy-to-understand but somewhat abbreviated form – as they are commonly referred to. For instance: the full title of the above Directive is *DIRECTIVE 2001/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 December 2001 on general product safety.*

   This was even an example of a short title – sometimes the subject of the provision itself takes two or three lines (eg: *DIRECTIVE 2014/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits*).

2. When searching on EUR-Lex, always look for the consolidated version of a relevant provision. This shows the provision 'as it currently stands', with all additions and modifications. Example: Directive 2001/95/EC has been amended by Regulations (EC) 765/2008 and 596/2009.

3. A little insight into EU legislation:
   This consists mainly of *primary law* (the founding treaties – of Maastricht, Lisbon, etc)
   and *secondary law* (EU regulations, directives and decisions).

   Regulations – apply directly throughout the EU; in all Member States. They can therefore be issued only where the EU has relevant competence (eg: not in the areas of taxation, national internal security, etc).

   Directives – do not apply directly; Member States are obliged to incorporate (technically speaking: transpose or implement) them into their national legislations within a specified time.
   (In Czechia, this is mostly done by government decrees; sometimes also by acts or ministerial decrees. – Eg: above mentioned Directive 2001/95/EC is implemented by Act 102/2001.)

   Decisions – have always a specific addressee. It can be, eg, a Member State (a decision on a fine) or it can be directed 'inside the EU itself'. An example is Decision 768/2008/EC, referred to below, which provides a kind of obligatory template that is copied into a number of other EU Directives/Regulations on product selling.

4. One more comment to the English term *regulation*:
   Beside the meaning mentioned above – one class of EU secondary law – it can also be understood more generally: as a synonym to *rule*, *provision*, or *prescript*. This covers all binding instructions, like *acts*, *directives*, *decrees*, *orders*, *standards*, as well as *internal procedures*.

   For distinguishing those two meanings in this Guide, the narrower one will be preferably written with capital first letter (*EU Regulation*) while the wider meaning is preferably quoted as *provisions* or *technical specifications*.

5. The last comment relates once again to the General Safety Directive.
   This describes, among other things, implementing of the *Rapid Alert System for Dangerous Products* (RAPEX).

As soon as a potentially dangerous product has been identifier, RAPEX enables all Member States to take rapid and effective actions to eliminate the risks – usually withdrawal of the product from the market. Although RAPEX is an important tool, we are only mentioning it in a note because we hope that a manufacturer or retailer will not encounter it in practice.

2.1. CE-marked products

Not all products on the market carry the CE marking – some examples (cars, foodstuffs) have been already mentioned. **(CE) is therefore not a completely generic marking and it is forbidden to be applied onto products for which it is not explicitly intended. It is neither a quality mark, nor does it evaluate its effectiveness or usefulness to users** as many people think.

For many products, this label does not even mean an *approved* or *certified* product.

For example, if you buy a CE-marked electric oven, this marking only guarantees that it meets the requirements of the relevant provisions, but not at all that it bakes well.

CE marking means that:

- **The product is regulated by specific European provisions that require this label.**
- **The product complies (is conforming) with all relevant requirements of these provisions.**
- **The manufacturer has issued a EU Declaration of Conformity (DoC) listing these requirements, and the conformity has been certified in the stipulated way.**

EEE also belong to CE marked products. The relevant provisions are discussed in Chapter 4

The provisions for each product group have evolved with the development of the EEC common market and later EC and EU. Originally, specific provisions and standards regulated the required characteristics of each product group. However, with a large number of them, they were not very uniform: the used terminology varied, requirements were sometimes too mild for one product too strict for a similar one, and there were significant differences between national standards and provisions. Proving the marketability of a product was often a very complex issue and could lead to inconsistent results. It often had to be carried out repeatedly for different countries of the European Community.

2.2. New and Global Approach

There were two things which essentially contributed to the unification of product requirements in the EU:

Unified European standards (abbreviated as EN) – which are usually only translated, or even directly adopted to national standard systems in English language.

National requirements may exist, but they shall not deviate from the EN requirements to the extent that they would constitute an obstacle to the single market (and free movement of goods in the whole EU).

Example: the Czech or German standards CSN EN 60335-1 or DIN EN 60335-1 are derived from EN 60335-1. If a product complies with one of these national standards, it complies to all of them.

Another important step were the so-called **New Approach and Global Approach documents** issued by the European Council in the early 1990s.

The *New Approach* established a general principle that, for large groups of products (for example: construction products or medical devices), **the EU would issue a basic provision** – usually a Directive, recently also a Regulation – which contains a definition of the group (positive and negative, ie which products are included and which are excluded) and very general basic requirements. These requirements are then specified in ENs which refer to the basic document and develop its requirements and vocabulary. **Such standards are branded as *harmonized* ones (hEN).**

While the basic guidelines of the New Approach are not considered as technical documents (they are addressed to the general public and potential consumers), the harmonised standards are *technical specifications* (they are primarily addressed to product designers and manufacturers).

The general principle is that if a product meets the requirements of the relevant harmonised standards, it also meets the basic requirements of the New Approach.

The manufacturer may choose to meet the essential requirements of the provisions otherwise than by applying the harmonised standards (eg by carrying out tests on a different type of test equipment than prescribed by the standard). However, they are responsible for ensuring that the results of the tests or assessments are at least at the level required by the standard. They shall also demonstrate that the test procedures were equivalent or comparable to the harmonised procedures.

The *Global Approach* added some more pieces to the unified 'mosaic'. It specified how conformity is demonstrated for each product group and sub-group. For this purpose, it defined a set of conformity assessment procedures (modules) labelled with A – H letters. Each module specifies what the manufacturer – ie the entity responsible for the conformity of the products with the requirements – must do, and whether another independent body has to be involved. Such body is usually called the *Announced Subject* or *Notified Body* – see Chapter 7.1.

The Global Approach includes an important principle: if a product has been properly assessed for conformity in one Member State, the assessment result is valid everywhere in the EU, and the product can be sold in all other Member States.

For more information on the New & Global Approach principles, see the so called *Blue Guide* published by the European Commission.

The conformity assessment modules are described, eg, in Decision 768/2008/EC. Although this Decision is not directly binding for either Member States or manufacturers, it serves as a template for the development of new versions of provisions related to the CE-concept.

Roughly speaking, the modules are getting stricter from A to H. If Module A is required, the manufacturer is responsible for assessing and demonstrating conformity by himself, and no one else is involved. On the contrary, Module H obliges the manufacturer to operate an approved quality management system and a selected Notified Body carries out continuous surveillance of this system.

Each New Approach Directive/Regulation specifies the assessment modules for the relevant product group. Sometimes the procedures may differ depending on the product category – eg, for toys for children under three (some of them may have an electrical part) a third party assessment is mandatory, while for other toys it can be carried out solely by the manufacturer.

Sometimes, a combination of assessment modules may be prescribed (eg sample testing plus periodic factory inspections), and sometimes the manufacturer can choose from the modules or combinations for a given product category.

In addition to the hierarchy of requirements and procedures for demonstrating conformity, the New and Global Approach also define the institution of Notified Bodies, the system for selecting them and proving their qualifications, and also the obligation of the manufacturer to issue a DoC and affix CE marking onto the products (after verification of conformity with the requirements according to the prescribed module).

To summarise: **In order to be traded on the single European market, a product** does not, strictly speaking, have to be of high quality, efficient or environmentally friendly, but it **has to comply with all relevant EU requirements for the product type**, which concerns both the characteristics of the product itself and the procedure for demonstrating conformity.

The following products are usually not taken as product for the EU market:

_ Products with a special purpose (and therefore with special rules for production and also trading) – eg products for military and security, space applications, special research, collectibles, etc.

_ Case-by-case designed products, manufactured and installed for a specific user (eg a production line or interior furnishings assembled for a specific customer). While such products shall also comply with the general safety requirements, CE marking is not required and the extent of any testing and proof of conformity is a matter for agreement between the supplier and customer.

The following is not considered as placing products on the EU market:

_ Transport of products from the manufacturer to the importer or authorized representative
_ Import into the EU for the purpose of re-exportation, ie as part of processing procedures
_ Manufacture in the EU determined solely for export to third countries
_ Display of products at trade fairs and exhibitions.

3. Obligations of operators in the EU market

An economic operator (natural or legal person) intending to sell an EuP on the EU market may be in the position of a manufacturer, importer, distributor or authorised representative, as appropriate.

Manufacturer

is a body who manufactures a product or has the product designed or manufactured, and markets that product under his name or trademark.

Authorised representative

means a body established in the EU who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.

Importer

is a body established in the EU who places a product from a third country on the EU market.

Importers must be from 'third countries' (outside the EU).
Anyone who sells a product made in another EU country is not an importer, but a distributor.

Distributor

is a body in the supply chain, other than the manufacturer or importer, who makes a product available on the market.

1. Note that the manufacturer is seen as primarily responsible for the product and its conformity to requirements. It is therefore irrelevant to what extent, if any, the 'manufacturer' is involved in the factual production. (An example might be a brand name "TESCO Milk".)
2. It often happens that goods imported from distant countries, where awareness of EU legislation is insufficient, do not meet all the requirements for proving conformity. In addition to being an *interpreter* of requirements and procedures to the foreign supplier, the *importer* has the following additional options:

   _To agree with the manufacturer and obtain a mandate as his authorized representative – and then the importer can assist in the conformity proving (eg by ordering the necessary tests from an accredited laboratory)

   _To declare himself as the manufacturer and to sell the goods under his own brand. However, he shall fulfil all the following obligations of the manufacturer and takes full responsibility for the goods.
3. The following obligations are listed in Annex I of Decision 768/2008/EC.

All the above mentioned operators shall, at the request of the market surveillance authorities and for a period proportionate to the lifetime of the product and the level of risk, identify:

_ All economic operators who have supplied them with the product,

_ All economic operators to whom they have supplied the product.

3.1. Specific obligations of the manufacturer

_ Ensure that products have been designed and manufactured in accordance with the requirements set out in relevant EU provisions

Essential requirements are quoted in EU Directives or Regulations,
and consequently in harmonized standards derived from them.

_ Draw up the required technical documentation

The documentation must enable assessment of conformity of the product with the relevant requirements. It shall specify the applicable requirements and, to the extent necessary for the assessment,
describe the design, manufacture and operation of the product.

It usually contains at least the following elements:

_ General description of the product
_ Design concept and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.
_ Descriptions and explanations necessary to understand the drawings, diagrams and the operation of the product
_ Risk analysis and risk assessment
_ List of relevant harmonized standards or other applicable technical specifications
_ Results of design calculations or checks carried out, test reports, etc.

Where the manufacturer does not manufacture the goods themselves, or takes over significant components from subcontractors, and where parts of the documentation (eg manufacturing drawings, or test results) indicate another manufacturer or product name, they shall credibly demonstrate that it is the same product or component.

For market surveillance authorities, the documentation must be submitted in physical or electronic form – a link to a website is usually not sufficient.

_ Identify properly himself and the product (on the product itself, or, where the size or nature of the product does not allow it, on the packaging or in a document accompanying the product) **and provide any other information requested**

To indicate the name and model of the product, or, where applicable, the series or serial number or any other information allowing the identification.

In addition, to state his name, registered trade name or trade mark
and an address at which he can be contacted. (A web address of a functioning website may be acceptable.)

For EEE, the *other information requested* may include, for example:

_ Voltage and power consumption of the product
_ Class of electrical protection
_ Degree of protection by the enclosure (is so called IP coefficient: dust and water resistance)
_ Safety warning or icon (eg "HOT SURFACE!")

_ Attach to the product the necessary instructions and safety information
in a language that consumers and other end users can easily understand.

In the Czech market, only the Czech language is acceptable. English and other European languages are not considered sufficiently understandable – they are, nevertheless, acceptable for *technical* product documentation – ie: not for *user* documentation.

In general, the language used for technical documentation must be understandable to a third party – eg a testing laboratory, certification body or market surveillance body. (In Czechia, there is usually no problem with the acceptability of Slovak and English. In many cases German or Russian are also accepted. But it is always a matter of agreement: if the language is not accepted, the submitter of the documentation is obliged to provide a Czech version.)

The manufacturer can either produce the appropriate language version himself or through an authorised representative (or, alternatively, through the importer).

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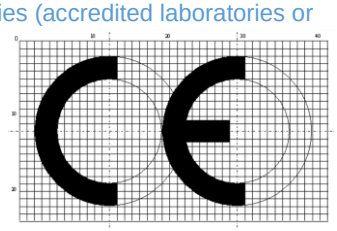
The necessary instructions relate in particular to:

_ Understanding the purpose of the product and all its functions
_ Necessary warnings, cautions, and risk descriptions
_ Description of all modes of operation, controls and procedures, the relationship between them,
and the conditions of use
_ Cleaning and maintenance instructions
_ Allowed user repairs and/or contacts to authorizes repair centres
_ Operating conditions (eg operating temperature and humidity, or restrictions for product placing)
and, if necessary, conditions for the installation, transport, and storage of the products

_ Carry out or have carried out the relevant conformity assessment procedure

The prescribed conformity assessment procedure is specified in the basic provisions. For procedures B to H, the involvement of a prescribed third party (notified body or announced subject) is necessary. If procedure A is prescribed, the manufacturer does everything by himself. If he uses services of third parties (accredited laboratories or certification bodies), this testing or certification is voluntary.

**_ In case of positive assessment result: to draw up
the EU Declaration of Conformity (DoC) and affix the conformity marking.**



Ie: CE marking, according to the template
presented in Annex II to Regulation (EC) 765/2008.

The DoC must be drawn up by the manufacturer –
it is an expression of acceptance of responsibility for the conformity.
If the DoC is drawn up by another entity on the market – an importer or distributor – this is taken as an administrative offence (delict).

**_ Implement procedures
to ensure that mass production remains in conformity with the requirements.**

Due account should be taken of changes in product design or parameters, and changes in harmonized standards or technical specifications.

Where deemed appropriate, due to the risks posed by the product, carry out repeated sample tests and keep records of complaints, non-conforming products and product recalls. Inform distributors of relevant facts, as well as the certification body if a Certificate of Conformity has been issued.

A situation where the majority of production process is located somewhere else than at the final manufacturer (often outside the EU) may pose an increased risk. The final manufacturer is then obliged to pay particular attention to setting up conditions and procedures ensuring that the conformity of the product (and all of its components) with all requirements is continuously maintained and verified.

_ Keep the technical documentation and the DoC for at least ten years after the product has been placed on the market.

_ If the manufacturer has any reason to believe that the product he has placed on the market is not in conformity with the relevant EU harmonisation rules:

-- Take immediately the necessary corrective actions in order to bring the product into conformity, or withdraw it from the market or from circulation

-- Where, in addition, the product presents an increased risk, immediately inform the competent national authorities (market surveillance authorities) of the Member States in which the product has been made available, giving details of the nonconformity and of the corrective actions taken

In the Czech Republic, this national authority is, for most product types, the Czech Trade Inspection Authority.

_ Submit to the competent national authority, on reasoned request, within a reasonable period of time, all information and documentation necessary to demonstrate the conformity of the product in a language which that authority can easily understand

3.2. Common obligations of importers and distributors

_ Place only such products on the EU market that are in conformity with all with the relevant provisions

_ Ensure that the product:

-- Bears the required conformity marking and identification marks of the manufacturer (and importer, where applicable)

-- Is accompanied by instructions and safety information in the language that consumers and other end-users can easily understand.

The extent of information for users can be stipulated, besides the New Approach provisions, by national regulations (In Czechia, for instance, by the Czech Consumer Protection Act).

_ Ensure that, while they are responsible for the product, storage and transport conditions do not jeopardize the conformity of the product with the requirements laid down in the relevant provisions

_ If the importer/distributor has any reason to believe that the product does is not in conformity with all relevant regulations, he shall not place the product on the EU market until it is brought into conformity. If the product presents a risk, the importer shall inform the manufacturer (or distributor shall inform the importer) as well as the market surveillance authorities.

_ If the product has already been placed on the EU market and is not in conformity with the relevant EU regulations, the importer shall immediately take the necessary corrective measures to bring the product into conformity or, where appropriate, withdraw it from the market or from circulation.

-- Where, in addition, the product presents an increased risk, immediately inform the competent national authorities (market surveillance authorities) of the Member States in which the product has been made available, giving details of the nonconformity and of the corrective actions taken

_ Submit to the competent national authority, on reasoned request, within a reasonable period of time, all information and documentation necessary to demonstrate the conformity of the product in a language which that authority can easily understand. He shall cooperate with that authority, at its request, on any actions taken to eliminate the risks posed by products which he has made available on the market

3.3. Obligations of importers

Importer – in addition to the obligations set out in the previous chapter:

_ Before placing the product on the market, ensure that:

-- the manufacturer has carried out the appropriate conformity assessment procedure

-- and has drawn up the required technical documentation

_ Indicates his name, registered trade name or trade mark and contact address
on the product or, if this is not possible, on the packaging or in a document accompanying the product.

_ In all cases where this is necessary to protect the health and safety of consumers:

- carry out tests on samples of products placed on the market
- investigate and keep records of complaints, non-conforming products and product withdrawals
- keep distributors informed of the results of these investigations.

_ Keep a copy of the EU Declaration of Conformity for the use of the market surveillance authorities for a period of ten years and ensure that the technical documentation (in an intelligible language) can be made available to these authorities on request.

3.4. Obligations of distributors

Before placing the product on the market, the distributor shall verify that:

_ The product bears the required conformity markings and identification marks of the manufacturer (and importer, if applicable)

_ The product is accompanied by documents and instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the product is placed on the market, and that the manufacturer and the importer have complied with the requirements set out in the preceding chapters

_ The manufacturer or importer has a valid EU Declaration of Conformity and the prescribed documentation.

3.5. Duties of authorized representatives

The manufacturer may appoint, in writing, his authorized representative. The representative shall carry out only the specific tasks set out in the Power of Attorney received from the manufacturer.

1. The Power of Attorney shall empower the authorized representative to at least:

   _ Keeping the EU Declaration of Conformity (DoC) and the technical documentation for the use of the national market surveillance authorities

   _ Supplying the competent national authorities, on reasoned request, with all the information and documentation necessary to demonstrate the conformity of the product

   _ Cooperation with the competent national authorities, when requested to do so, on activities to eliminate risks arising from products covered by its mandate.

2. The authorized representative shall not be responsible for the design, manufacture, and conformity of the product and for drawing up the technical documentation.
   (However, some New Approach provisions may restrict or extend the scope of the competences allowed.)

What does an authorized representative usually do?

_ Interprets non-EU regulatory requirements to manufacturers
_ Co-operates in obtaining proofs of conformity (eg: tests, voluntary certification where appropriate)
_ Communicates with market surveillance authorities

_ Co-operates in completing the manufacturer's documentation (eg: user instructions), product labelling (eg: attaching a new label based on EU requirements, addition of CE marking), or in drawing up DoC

_ Keeps the DoC and the technical documentation (in understandable language) for the use of the national inspection authorities.

4. Essential provisions for EEE relating to CE marking

There may be a number of provisions for EEE that must be complied when placing them on the EU market. The four most typical ones are listed below:

Area (aspect)	EU Directive
Electric safety	**2014/35/EU** *on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits*
Electromagnetic compatibility	**2014/30/EU** *on the harmonisation of the laws of the Member States relating to electromagnetic compatibility*
Prohibited substances	**2011/65/EU** *on the restriction of the use of certain hazardous substances in electrical and electronic equipment* (modified by Directives **(EU) 2015/863, 2017/2102 a 2019/178**)
Eco-design	**2009/125/ES** *establishing a framework for the setting of ecodesign requirements for energy-related products*

However, these provisions are not necessarily the only ones which are relevant for an EEE. Other provisions that are related to the function of the product (eg: for machines, toys, or radio equipment) are mentioned in Chapter 5.

For all the directives listed in this chapter, Procedure A is prescribed for conformity assessment (see Chapter 2.2). This means that the **conformity assessment is the responsibility of the manufacturer** and if he asks for assistance from a third party (eg: laboratory, certification or consulting body), it is voluntary.

Let us mention here the fact that there are also international certification systems that are voluntary, too, but are globally recognised and can facilitate the export of EEE to other territories outside the EU – such as the IECEE-CB System (see Chapter 7.3 for a link). The use of these systems can decrease testing and certification costs, but does not relieve the manufacturer of any of the obligations listed in Chapter 3.2 – ie: to gather evidences of conformity, to issue the EU Declaration of Conformity, and to affix CE-marking onto the products (provided they are intended to be sold in the EU).

Thus, **for most conventional EEE, no 'CE certificate' or any other third party document is mandatory when placed on the market – only a DoC issued by the manufacturer.**
Examples of exceptions are described in Chapter 5.

4.1. Electrical safety (LVD)

The LVD (Low Voltage Directive) applies to EEE intended for use in the voltage ranges of 50 – 1,000 V AC or 75 – 1,500 V DC.

These limits indicate the input or output voltage – the EEE itself may have a higher internal voltages.

LVD does not apply to:

_ EEE intended for use in potentially explosive atmospheres
_ EEE intended for radiological and medical purposes
_ Components for lifts
_ Electric meters
_ Household sockets and plugs
_ EEE for supplying power to electric fences
_ EEE for radio communication or interference
_ Special EEE for use in transport vehicles
_ Special kits exclusively for use in research and development facilities

A frequent question is whether EEE powered by adapters are covered by the Directive.

If the adapter is a separate component, or the product is sold without any adapter and can operate with any source of the prescribed output parameters (below 75 V DC), the conformity with LVD requirements does not need to be demonstrated. (The adapter itself, however, falls under LVD and shall have its own DoC and CE marking.)

If the adapter is an integral part of the equipment, the product falls under LVD. Even then, however, the requirements can be automatically satisfied by the adapter being CE-marked and the electrical scheme showing that the rest of the product is below the LVD lower voltage limit.

In general, **LVD applies both to EEE for direct use and for incorporation into other devices – ie components.** However, some components are of such a nature that their safety depends to a large extent on

how they are incorporated into the final product and on the overall characteristics of that product. These are not covered by LVD and are not CE-marked.

Examples of components out of LVD scope are:

_ Passive components such as capacitors, inductors, resistors, or filters
_ Electro-mechanical components such as connectors, some relays, or micro-switches
_ Active components such as diodes, transistors, thyristors, or rectifiers, triacs, optoelectronic semiconductors, or integrated circuits

However, some other components fall under LVD, eg:

_ Wires and cables
_ Distribution and control cabinets (only cabinets without accessories)
_ Some types of transformers and electric motors

The safety requirements set out in Annex I to the Directive are very general, and they are specified in the relevant harmonized standards.

Examples of frequently applied standards:

_ EN 60598-1 – luminaires
_ EN 61010-1 – measuring and laboratory instruments
_ EN 60335-1 – household appliances

The last two standards have in common that their requirements are further developed in a number of other subordinate standards. For example, EN 60335-2-2 covers vacuum cleaners, -2-3 covers irons, -2-4 covers centrifuges, and on and on, up to -2-90 covering microwave ovens, and -2-109 covering water treatment equipment. – There are, in short, hundreds of harmonized standards with precise requirements.

4.2. Electromagnetic Compatibility (EMC)

The EMC (ElectroMagnetic Compatibility) directive applies to any EEE that may be a source of electromagnetic interference, or whose operation may, under normal operating conditions, be affected by electromagnetic interferences.

Thus, for EMC, two areas are always examined: emissions and immunity.

Simply in examples:
an electric reclining bed in a hospital shall not be so poorly designed as to switch off a patient's pacemaker. And an air-conditioning control in a large poultry farm must not be designed so that a voltage surge in the mains supply sets it in wrong mode or shuts it down.

Simply said, EMC applies to those **EEE that contain active electronic components** – those that generate or can generate electromagnetic waves or can be substantially affected by them.

Examples of active elements are given in the previous chapter. – On the contrary: an example of a passive device that does not need to be EMC verified is an ordinary lamp: a power cord, a switch, and a conventional bulb. (However, a luminaire with a sensor, LED or fluorescent lamp and ballast is a different case.)

The following are further exempted from the scope of the EMC:

_ Radio devices (eg: EEE with remote control, or communicating via WiFi or BlueTooth)

Note: the exemption from the Directive does not mean that radio equipment is exempt from EMC requirements. However, they are applied under the RED priority directive (2014/53/EU *on radio equipment* – see chapter 5.2).

_ EEE for air traffic

_ Dedicated sets exclusively for use in research and development facilities.

_ EEE which have physical characteristics such that they:
-- cannot cause electromagnetic emissions, which exceeds a level that would allow radio and telecommunications equipment and other equipment to function in accordance with their intended use, nor contribute to such radiation
-- operate without unacceptable deterioration in the presence of electromagnetic interferences, which are normal to their operation in accordance with their intended use.

Note:
This point is specified in the relevant harmonized standards. Example: A reflective warning element fitted with flashing LEDs has been tested for emissions according to EN 55014-1. It fulfils the immunity requirements of EN 55014-2 (as "EZ without electronic control circuitry") – without testing.

EMC test results can be quite sensitive to any modification of the product (component substitution, housing material, or so) – the product parameters can change significantly.

While conformity with LVD for a final product can sometimes be derived from the conformity of components that have their own CE marking, and the LVD tests can be therefore reduced, much more caution is needed for EMC. Irrespective of component compliance, it is almost always necessary to test the complete product or assembly, under simulated operating conditions (load, temperature, humidity, in all operation modes, etc).

EMC 'sensitivity' can also have practical implications where the manufacturer offers a range of models in the same product line.

While for LVD it is usually sufficient to test the conformity of the 'most powerful' model (in terms of performance and components used) and then, in case of a positive results, to infer the conformity for all other models, for EMC it is advisable to be more cautious: first thoroughly investigate all differences between the models and their possible impact on EMC and then, if necessary, in addition to the complete tests for the selected model, perform random reduced tests for another 'most different' model. If the test results are significantly different, a thorough evaluation of the situation should be made and a decision taken to extend the scope of the necessary testing.

Whereas the harmonized standards for LVD are clearly determined by the type and intended use of the product, for EMC it is often possible to choose alternative ways of demonstrating conformity – either according to the use of the product, or to the environment in which it is going to operate.

Examples of standards by application:

_ EN 55014-x – Household EEE, electrical tools and similar apparatus
_ EN 55015 – Luminaires
_ EN 55032 – IT devices

Examples of standards for the environment:

_ EN 61000-6-x – Generic standards for residential, commercial and light industrial environments

4.3. Restriction of Hazardous Substances (RoHS)

While LVD and EMC were concerned with the risks during the operation of an EEE, RoHS is primarily concerned with the risks in the disposal of the EEE – ie industrial waste. This is because typically used EEE may contain substances that are harmful to health, difficult to degrade, and environmentally damaging. Therefore, **the RoHS Directive prohibits the use of the following ten groups of hazardous substances in EEE:**

- **Four elements: cadmium, lead, mercury and hexavalent chromium.**
- **Two groups of organic bromine compounds – Polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE).**
- **Four types of phthalates – bis(2-ethylhexyl)phthalate (DEHP), butylbenzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).**

A maximum of 0.01% cadmium and 0.1% of the other nine prohibited groups are tolerated in the individual homogeneous materials used in the EEE.

The Directive contains a number of exemptions, both for same EEE families, and for individual materials.

1. RoHS does not apply to:

   _ EEE for protection of national security interests
   _ EEE intended to be sent into space
   _ Large stationary industrial tools and large fixed installations (large machines, production lines, etc)
   _ Means of transport other than electric two-track vehicles for which type-approval has not been granted;
   _ Active implantable medical devices;
   _ Photovoltaic panels
   _ EEE specifically designed for research and development purposes only

   For a precise description of the above groups, see §4 of the Directive.

2. Annex III to the RoHS Directive lists restrictions for individual materials and specific uses. There are around forty exemptions (some of which define further sub-groups and the total number is therefore actually much higher) and they are amended over time due to technical progress (usually tightening or adding new ones). Restrictions vary – some are in units of weight, while some others are time limited.
   A full list of these is beyond the scope of this brief guide.

   Some examples:
   _ Restriction 1c allows mercury in single-wire compact fluorescent lamps of 50-150 W,

up to 5 mg per fluorescent lamp.
_ Restriction 6c allows up to 4% lead in copper alloys.
_ Restriction 9b allows lead in bearing pans in compressors containing refrigerant in systems for heating, ventilation, air conditioning and refrigeration in monitoring and control equipment until July 21, 2024.

The RoHS rules – for they generally apply to all homogeneous materials in all EEE – are quite strict. An EEEE typically contain dozens and sometimes hundreds of different materials. Obtaining evidence of compliance – ie laboratory analysis of materials – is quite expensive. Therefore, final manufacturers usually use the 'pyramid system': they demand proofs of conformity from their suppliers or subcontractors.

A credible evidence can be a certificate, even better is a test report with the results of the relevant tests. A DoC issued by a material or component supplier, unless supported by other evidence, is usually not sufficient proof.

EEE manufacturers are advised to follow the provisions of the only harmonised standard on RoHS: EN 50581 *Technical documentation for the assessment of EEE for the control of hazardous substances*. It requires that a system for control of the documentation has to be established and permanently maintained. This system should be described and should define the method of procuring and verifying evidence documents, the criteria of credibility and the measures for maintaining and increasing the evidential value of RoHS documentation.

Example:
A test report from an accredited laboratory supplied by a subcontractor who is also certified for a quality management system (ISO 9001) and can boast a number of references as a supplier to major European companies will certainly have a higher weight on the credibility scale than a mere DoC from an unknown supplier created electronically (ie in such a way that the stamp and signature have been electronically inserted into the text and, therefore, the authentic original document does not exist at all.
Whereas in the first case it is sufficient to verify periodically that there have been no significant changes in production and that the supplies correspond to the product or material tested, in the second case the supplier should be pushed to provide more authentic evidences of conformity. If this efforts are not effective, either the subcontractor should be replaced, or the final manufacturer can have the relevant tests carried out ourselves at his own expense.

As RoHS concerns waste rather than the products themselves, let us also briefly mention the fact that sellers – ie not only manufacturers and importers, but all entities that supply EEE to the market – are subject to **obligations under the national provisions regarding wastes**. They may be different in each EU member country.

4.4. Ecodesign (ErP)

The Ecodesign Directive 2009/125/EC (various abbreviations are used; the most common is ErP: Energy-related Products) **requires manufacturers to take environmental requirements into account in product design and production.**

1. The Directive covers all stages of the product's life cycle: selection and use of raw materials, production, packaging, transport and distribution, installation, use and maintenance until the end of life (ie disposal or recycling).
2. For each phase, the following environmental aspects should be assessed:

   _ the expected consumption of materials, energy and other resources such as water
   _ anticipated emissions to air, water or soil
   _ anticipated pollution of the environment by physical effects such as noise, vibration, radiation, electromagnetic fields, etc
   _ projected quantities of waste material produced
   _ possibility of reuse, recycling and recovery of material or energy

   And the manufacturer should minimise negative impacts.

The Directive itself does not impose specific tasks or even require documentation related to this assessment and the measures taken. It **is**, however, **the starting point for a number of EU Regulations that specify general requirements for certain product groups.**

in the same way as harmonised standards do for other directives.

At the time of publication of this guide, over thirty such provisions have been published. **If a product is covered by one of these Regulations, all the requirements** (usually listed in the annexes to the Regulation) **must be met when the product is placed on the market, and the conformity must be mentioned in the DoC.**

These particular Regulations cover, for example, hobs and ovens, vacuum cleaners, computers and servers, refrigerators, TV sets, fans, pumps, washing machines, dryers, selected light fittings, electric motors, heating systems and heaters, etc.

As with directives and standards, the positive and negative definitions of the scope of the Regulation (ie: what is included and what are the exceptions) need to be carefully studied. For example, microwave ovens, small and portable ovens, grills, heat storage ovens and a number of other subgroups are exempted from Regulation (EU) 66/2014.

A frequently applied Regulation is (EC) 1275/2008, which prescribes maximum power consumption limits for EEE intended for households and offices in off and standby modes (eg when the copy machine is not working but the display is on).

A number of product groups for which specific ecodesign Regulations exist (eg: household appliances) are also covered by **Energy Labelling Regulations**. These **are** as **binding** as ecodesign, **but** are **not mentioned in DoC** or governed by other rules of the New Approach.

5. Other provisions possibly binding for EEE

In addition to the four 'basic' directives listed in the previous chapter, **EEE may also fall within the scope of other provisions related to CE marking.**

We use the generic term provision because these are either EU Directives, or Regulations.

These are linked to the intended use of the EEE and usually take precedence over LVD and EMC Directivs. Indeed, their harmonized standards usually include or refer to electrical safety and magnetic compatibility assessments. **It is therefore advisable to get familiar with the list of relevant provisions (on the NANDO portal)**, and, if the product could fall under one of them, to study the scope of the provision as well as the relevant harmonized standards, and to obtain evidences of conformity with their requirements.

Some of these provisions partially modify LVD or EMC requirements, and explicitly state that conformity with LVD or EMC need not be demonstrated and mentioned in the DoC.

Some examples of these 'preferential' categories of CE marked EEE:

_ radio equipment (eg: remote-controlled EEE, clever buildings, Internet of Things)
_ medical devices (dialysis machine)
_ measuring instruments (electricity meter)
_ toys (talking doll, drone)
_ building products (building alarm and security systems)
_ machinery (lathe)
_ personal protective equipment (safety vest with flashing elements)

Remember that some of these provisions (eg some measuring instruments, dangerous machinery, building security systems for buildings, medical devices, or toys for children under three years) **may require mandatory third-party certification.**

The following three sub-chapters deal with machinery, radio equipment and medical devices.
If your EEE does not fall under these, skip them.

5.1. Machinery

***Machinery* is anything containing moving parts,**
and powered by energy other than human or animal energy.

With the exception of some lifting equipment which may be powered by human power.

The range of components and accessories for machinery (eg safety components, chains, removable gears, etc – for details see Article 1.1 of the Directive) also fall under **Directive 2006/42/EC, hereafter in this chapter MD** (Machinery Directive).

Among others, the following are excluded from the scope of MD:

- The following EEE which are covered by LVD:
  _ household appliances for domestic use
  _ audio and video equipment
  _ information technology equipment

_ ordinary office machines
_ low-voltage switches and control units
_ electric motors

So: a large industrial lathe will have to be assessed under MD,
while a kitchen processor or a handheld hobby drill will not.

- Weapons and equipment for military and security use, nuclear equipment, naval vessels and many types of transport equipment, research and laboratory equipment, mining and quarrying equipment
- High-voltage switching and control equipment and transformers

Annex I of MD lists the requirements for machinery – from general ones to specific for selected types of machinery. They are given in sufficient detail and provide a good basis for conformity assessment (the Annex is over 40 pages long).

Annex IV lists 'dangerous machines' – ie those where conformity assessment may involve a third party (Notified Body).

These include, for example, manually operated milling machines, circular or chain saws, plastic and rubber presses, certain safety shields or casings, service jacks for vehicles, etc.

Conformity assessment (Article 12 of MD):

- **Where the machinery is not referred to in Annex IV, the assessment shall be carried out by Internal Production Control – ie: by the manufacturer's own efforts, without an assistance of a third party.**

The procedure is described in Annex VIII of the Directive and corresponds to Procedure A of the Global Approach.

It requires that the manufacturer:

_ Draws up for each design series model the technical documentation listed in Annex VII.

_ Takes all necessary measures in order to ensure that the manufacturing process ensures that the machinery produced conforms to the technical documentation and to the requirements of MD.

- **Where the machinery is referred to in Annex IV and if it has been manufactured in accordance with harmonised standards covering all the essential requirements of the Directive, the assessment shall be carried out by:**

_ Internal Production Control

_ Or by Type-examination (carried out by a Notified Body) together with subsequent Internal Production Control

_ Or by Full Quality Assurance (according to the quality assurance system approved and periodically surveiled by a Notified Body)

1. The harmonized standard must therefore exist. For some newly developed machinery, the relevant standards do not yet exist, or they have not been applied by the manufacturer for some reason.
2. Harmonized standards for machinery are of three types:

   _ Type A standards give basic concepts, principles for design, and general considerations that can be applied to all machinery. These are standards of the EN 12100(-x) family.

   _ Type B standards (group safety standards) deal with one safety aspect (eg: safety distances or surface temperatures) or one type of safety device (eg: two-hand controls or guards).

   _ Type C standards deal with detailed safety requirements for individual machine groups.
3. The Type-examination is described in Annex IX of the Directive and corresponds to Procedure B of the Global Approach. It prescribes type testing (ie: tests carried out on a sample of the product) carried out by the Notified Body, which issues a certificate in case of a positive result.
4. The Full Quality Assurance is described in Annex X of the Directive and corresponds to procedure H of the Global Approach. The manufacturer shall establish and maintain a quality assurance system (ie: ensure continuous conformity of products with all essential requirements of the Directive). The Notified Body shall inspect the production control system, issue a certificate in case of a positive result, and carry out regular (usually annual) surveillance inspections.

- **Where the machinery is referred to in Annex IV and if it has not been manufactured (in whole or in part) in accordance with harmonised standards covering all the essential requirements of the Directive, the assessment shall be carried out by:**

  _ **Type-examination (carried out by a Notified Body) together with subsequent Internal Production Control**

  _ **Or by Full Quality Assurance (according to the quality assurance system approved and periodically surveiled by a Notified Body)**

In this case, therefore, the Notified Person is always involved – either as a test laboratory, or as an inspection body.

The basic standard – EN 12100 – requires the manufacturer or designer of the machine to carry out a risk analysis, ie:

- Identification of the possible risks in the use of the machine
- Their assessment (in terms of possible consequences and probability of occurrence, over the lifetime of the machine)
- Measures to eliminate them (eg guards, inspection and maintenance schedules)

If the notified body will cooperate in the conformity assessment, this risk analysis will always be required in written form.

Machinery has, perhaps a little more than other product groups, the following specifics:

- **Incomplete machinery** (part of a machine or production line, etc.) – as a part of the preparation of the documentation, assembly instructions are required. Instead of a DoC, the manufacturer issues a Declaration of Incorporation of Partly Completed Machinery in accordance with Annex II of the Directive.
- **Used machinery** – when sold, it is generally not covered by the Directive. However, in some Member States it may be subject to national provisions.
- **Modified machinery before first use** – Some machinery may be sold as variable. If the modifications are described or approved by the manufacturer in advance, the DoC remains valid.

  If they are not, and if the changes are substantial – in particular those affecting the functions or performance of the equipment – a new risk analysis and a new conformity assessment are required.

5.2. Radio equipment

***Radio equipment* is an electrical product that intentionally emits and/or receives radio waves for the purpose of radio communication or radiodetermination. Radio waves are electromagnetic waves of frequencies below 3 000 GHz, propagated through space without artificial conduction.**

5. *Radiodetermination* means the determination of the position, speed or other characteristics of an object using radio waves (eg: radar or radio altimeter).
6. Devices that communicate via lines (eg fixed telephone or data lines, or security equipment) or use other types of waves (eg sound) or other frequencies (eg lasers) are not radio equipment.

   Similarly, EEE which do not emit electromagnetic waves for communication purposes (eg microwave ovens or certain surgical instruments) are not radio equipment.
7. Some radio equipment may be incomplete - e.g. without an antenna.
8. There is a wide range of radio devices, for example EEE communicating:

   _ In licensed bands (eg radio and television receivers or transmitters, mobile phones, or devices operating on special frequencies for defence and security purposes)

   _ via WiFi, BlueTooth, RFID, NFC networks, short-range networks (eg LoRa, SIGNET), etc

   _ via low-speed applications (eg IoT, Internet of Things)

Radio Equipment Directive 2014/53/EU (hereafter RED, Radio Equipment Directive) lists in Article 1 and Annex I the products not covered. These include the following EEE:

- Related to public security and defence
- Selected equipment for radio amateurs
- Aeronautical and maritime equipment
- Tailor-made equipment for research and development.

Article 3 of RED defines the essential requirements for radio equipment in the areas of:

- Electrical safety
- Electromagnetic compatibility
- Utilizing of the radio spectrum

**If the product meets all the requirements of the harmonized standards to the essential requirements of RED, it also meets the requirements of the LVD and EMC directives,
and therefore these directives are *not mentioned* on the EU Declaration of Conformity.**

Clarification of the previous sentence:
RED requirements sometimes modify the LVD and EMC requirements. While the EMC Directive primarily applies to EEE that do not or only minimally radiate electromagnetic waves, for radio equipment this radiation is the intention and one of the functions of the equipment. It can therefore exceed the EMC limits within the operating frequency band, but only in a specified way (in terms of power) and outside these frequencies it shall strictly comply with the limits. Testing under RED is therefore much more targeted and extensive than that for EMC.

Similarly, for electrical safety testing, the so-called zero voltage limit applies to all radio equipment. Tests are therefore always carried out; even for that equipment operating at voltages lower than LVD.

Conformity assessment (Article 17 of RED):

- **Where the EEE has been manufactured in accordance with relevant harmonized standards to RED, the assessment shall be carried out according to procedure A, or to procedures B+C, or procedure H.**

A harmonised standard must therefore exist. For some newly developed products or standards, the relevant standards do not exist yet, or have not been used by the manufacturer for some reason.

Procedure A (internal production control by the manufacturer) is described in Annex II to RED.

If a manufacturer chooses Procedure A, he should be sure that he can really demonstrate that each product produced complies with all the requirements of the harmonised standards. As the testing requires complex and expensive equipment, manufacturers usually contact a sufficiently qualified third party (accredited laboratory or certification body) and have the conformity assessment carried out externally.

Procedures B (type tests) and C (conformity to type based on internal production control) are described in Annex III to RED. The type tests are carried out by a Notified Body, which issues a certificate in case of a positive result.

Procedure H (full quality assurance) is described in Annex IV to RED. It means that the Notified Body will inspect the production management system, issue a certificate in the case of a positive result and carry out regular (usually annual) surveillance inspections.

- **Where the EEE has not been manufactured in accordance with relevant harmonized standards to RED, the assessment shall be done according to procedures B+C, or procedure H.**

In this case, the Notified Person is always involved – either as a test laboratory, or as an inspection body.

The RED explicitly prescribes that at least a simplified DoC has to be included in the user documentation to the radio equipment.

It does not have to be necessarily supplied separately, but can be included in the user manual or installation instructions.

5.3. Medical devices

***Medical device* (hereafter MedDev) is any product that meets the definition of a medical device as set out in Article 2 of the Medical Device Regulation (EU) 2017/745 (hereafter MDR).** The intended use of the device is essential and must be clearly defined by the manufacturer.

MedDev is an instrument, apparatus, equipment, software, implant, agent, material or other article intended by the manufacturer to be used in humans for one or more of the following specific therapeutic purposes:

_ Diagnosis, prevention, monitoring, prediction, prognosis, treatment, or mitigation of disease,
_ Diagnosis, monitoring, treatment, mitigation or compensation of an injury or disability,
_ Investigation, replacement or modification of an anatomical structure or physiological process or condition,
_ the Provision of information through in vitro testing in respect of samples derived from the human body.

MedDev also include so-called *active devices* whose operation depends on a source of energy that is not generated for this purpose by the human body or gravity. They are therefore also devices powered by electrical energy.

In order to place a MedDev on the market, the manufacturer must comply with the requirements of MDR using the classification rules set out in Annex VIII to MDR. **The initial step is to correctly classify the MedDev in the relevant risk class** as belonging to one of Class I, IIa, IIb or III.

Sometimes it happens that the manufacturer or importer has no idea that his EEE is also a MedDev (eg: electric breast pump, heating pad, or massage device), sometimes he hesitates with the correct classification. In each EU Member State, there is a competent authority that can decide on the classification (or non-classification) of an EEE as a MedDev. (In Czechia, this authority is the State Institute for Drug Control – www.sukl.eu).

If in doubt, the "Manual on Borderline and Classification" (reference in Chapter 73), which describes a number of specific product groups, may also be useful. However, this was issued for the European Medical Device Directive, which is no longer in force. No such manual has yet been issued for the MDR which replaced that directive.

For the classification of medical devices, there is a valid manual "Guidance on Classification of Medical Devices".

Depending on the classification of the MedDev, the manufacturer then applies the appropriate conformity assessment procedure, with a Notified Body being involved for most products (only some Class I devices are excluded).

The Notified Body is not required to assess the MedDev if it:

- Belongs to Class I (ie does not meet the conditions for inclusion in higher classes),
- And, at the same time, it has no measuring function, is not sterile, and is not a reusable surgical instrument.

Examples of such MedDev are examination lights or illuminated surgical microscopes, light sources for curing dental restorations, trolleys and chairs, or certain types of rehabilitation aids.

The relevant conformity assessment procedures are described in the following annexes to MDR:

- IX - Comprehensive quality assurance (sometimes containing also the product design assessment)
- X – Type-examination
- XI - Manufacturing quality assurance or product verification

The manufacturer shall carry out a number of mandatory actions before conformity assessment. These always include the preparation of the prescribed technical documentation (according to Annexes II and III to MDR), **which includes, inter alia, a risk analysis, and a clinical evaluation of the MedDev** (Chapter VI and Annex XIV of MDR).

The clinical evaluation may come out from either a literature survey, or comparison with equivalent MedDev types (ie: technical, biological, and clinical equivalence), or clinical testing (Annex XV to MDR).

5.4. Other provisions outside the New Approach

There may be additional mandatory requirements for some types of EEE that must be met. These may be of different types and some again require third party involvement.

One type is the national provisions of individual EU Member States.

An example [for Czechia] is the mandatory assessment (by an Authorised Body) of some selected construction products – eg electrical cables, switchgear, heat pumps etc. The relevant provision – Czech Government Decree 163/2002 – is a national provision and therefore applies only to the Czech market.

It is therefore, in a way, a violation of the principle of the single European market. But Czechia is no exception – most countries have similar national provisions. The primary reason is not to make things more complicated and to put trade barriers against the single market concept, but rather the fact that many products simply deserve provision and EU countries have not yet been able to agree on it. (The range of products covered by Decree 163/2002 was originally wider, but many products have already come under the EU Construction Products Regulation – CPR.)

So, if you want to sell EEE to be incorporated into buildings, you should get familiar with the requirements of this Decree and see if your product is covered.

Decree 163/2002 is not a part of the New Approach provisions and is therefore not tied to CE marking. But this does not mean that EEE falling within its scope will not be CE-marked. There may still be enough reasons left for CE marking: LVD, EMC and RoHS.

Another example would be provisions related to:

- **Special purpose of the product**

For example, EEE designed for:

_ Nuclear equipment
(Consult the National Nuclear Safety Authority here for provisions and requirements.)

_ Transportation applications (automotive, shipping, air and rail)
(Here, systems of approval provisions are in place,
as well as specifically mandated approval bodies and testing laboratories)

In addition, the automotive industry is characterised by the fact that, for both cars and their components, systems of industry and group standards are applied, replacing the lack of uniform European legislation)

- **The specific characteristics you want to guarantee for the product or which are required by the customer**

Eg increased fire resistance or cyber security.

A more detailed description of these provisions (especially for constantly evolving new product groups) is beyond the scope of this manual. **This guide also does not cover EEE for high currents** – ie using voltages above the upper limit of the LVD (1000 V AC or 1500 V DC). These EEE are of course subject to more stringent safety requirements and you should contact a testing or certification body with appropriate accreditation.

6. Brief summary: How to proceed

1. **If you have a choice, decide on your role in the distribution process.**
   Are you the producer or will you take over his role?
   Will you be the importer, or are you going to be commissioned as an authorised representative?

   Get familiar thoroughly with all your responsibilities – see Chapter 3.
   Either fulfil them, or demand them from the manufacturer or other operators in the distribution chain.

Further:
If you are the manufacturer (or are cooperating with the manufacturer in obtaining evidences of conformity for issuing produce the EU Declaration of Conformity):

2. **Learn about the provisions for CE marked products on the NANDO portal.**
   First, the names of the provisions,
   and, if any of them correspond to the purpose of your product, then its scope.
   If the product falls within the scope, provide evidence of compliance with the requirements.

The New Approach provisions usually have their interpretation documents (called Manual, Guide, or Guidance) - usually in English (but some of them translated to other languages). If you are in doubt about the classification (qualification) of your product, try to find the answer there. See chapter 7.3.

3. **Get familiar with any additional provisions resulting from the special nature of your EZ or the special features you want to guarantee.**

Find out in the provision what conformity assessment procedures are prescribed and whether you can carry out the assessment yourself, or whether a third party (accredited laboratory or certification body) is required

4. **If your product falls within the scope of the LVD and EMC directives** (see chapters 4.1 and 4.2) and is not excluded by other higher priority provisions (eg RED)**, provide evidence of conformity.**

You can provide the evidence yourself (testing in your own laboratory, assessment by yourselves),
or you can also ask for an assistance from a third party with appropriate qualifications.

The LVD and EMC directives are different,
but if you order tests from an accredited laboratory, they will usually carry them out at the same time.

5. **Unless your product is exempt from the RoHS Directive** (see chapter 4.3)**, get proof of conformity from your subcontractors for *all* components or materials supplied.**

For RoHS, too, you can obtain the evidences yourself (if you have money enough to do so).
Recommendation: apply the documentation control system according to EN 50581.

6. **Get familiar with the provisions for ecodesign** (and, where applicable, for energy labels).
If your product falls within the scope of one of the ErP Regulations (see chapter 4.4),
provide evidences of conformity.

Items 5 and 6 are among often neglected duties. Many manufacturers and importers are only somehow aware of LVD and EMC requirements, and unaware of the obligation to prove RoHS conformity, or they fulfil it very formally. Awareness of ErP provisions is even lower.

This may be because these obligations are historically younger and the risks associated with nonconformity are considered to be lower. But market surveillance authorities have been focusing on them recently, equating them with the more 'historical' LVD and EMC requirements.

7. **If you are the manufacturer,
draw up the EU Declaration of Conformity (DoC) and affix CE-marking onto all products.**

8. **Before placing products on the market,
reconsider the risks associated with the product
and get familiar with any additional provisions
(other than those associated with CE marking), that may apply to your product.**

Due to the scope of this guide, we will only briefly mention these with a few examples:

_ Special provisions may apply to EEE using radioactive materials, explosives and hazardous chemicals, e.g. lasers and other intense light sources.
It always depends on the amount and intensity of these potentially hazardous factors.

_ Quite often the provisions applied include requirements for materials in contact with water food or drinking water (kitchen appliances, EEE for water distribution and treatment, etc).

Confirmation of compliance with these special requirements is not related to the CE marking and therefore shall not be mentioned on DoC.

If you are not sure about all the requirements for a given EEE, you can contact the PROduct COntact Point.

These contact points are established in all EU Member States – so if you want to sell your products in other countries, they will provide you with information on any national provisions that apply to your product type.

9. **If you place products on the market, remember that all products shall comply
with the requirements – not just the sample being tested or assessed.**

_The manufacturer is primarily responsible for the conformity, but every link in the distribution chain is shares the responsibility.

_The manufacturer shall maintain a production control system that ensures continuous conformity of products.

_Any change of the product that may affect the conformity requires a new conformity assessment.

10. **Remember that some of your obligations continue
after the product has been placed on the market.**

_For example, documentation and in particular evidence of conformity prepared for market surveillance authorities, further: information on suppliers and customers and other data to enable product traceability, information obligations and measures when non-conforming products are found on the market, etc.

_Do not forget the obligations under waste and packaging legislation.

7. Terms, abbreviations, links

7.1. Useful terms

Accreditation

Accreditation (from French: *verifying credibility*) means the empowerment to an activity or the verification and recognition of such empowerment. It can often be synonymous with *obtaining a licence*. Accreditation for testing laboratories and certification bodies is issued by national accreditation bodies (eg: Czech Accreditation Institute). The scope of accreditation of all entities is verifiable on the website of the accrediting body.

National accreditation bodies are associated in international organisations – eg IAF, International Accreditation Forum. On its website you can find a link to the national accreditation body and then to the relevant accredited body anywhere in the world.

Test reports and certificates from accredited bodies are of course more trustworthy than non-accredited documents.

Authorisation and notification

Where provisions (national or European) require the involvement of a third party in conformity assessment (mandatory certification), this is carried out by authorised or notified bodies. (These are legal entities – ie organisations and not individuals.) In Czechia, authorisations are granted by COSMT (Czech Office for Standards, Metrology, and Testing), grounded on demonstrated competences of the applicant (usually accreditations).

Mandatory assessments under national provisions are carried out by *Authorised Bodies*. For assessments under European provisions, the national authorizing body informs (notifies) the European Commission on the Authorized Body (or any change of their competences), who thus becomes a *Notified Body*. Unfortunately, the terminology is not uniform – some New Approach provisions use the term *Announced Subject*.

The competence of the body to carry out accredited, authorised, or notified activities is regularly verified. The list of Notified Bodies can be found on the NANDO portal.

Conformity, Assessment of Conformity, EU Declaration of Conformity

In order to be placed on the single European market, a product must comply with all relevant requirements.

The term *conforming* (or sometimes *compliant*) has replaced the former terms quality, safe, innocuous, etc. Conformity is declared by the manufacturer in the *EU Declaration of Conformity* (DoC). There is only one declaration for a product and it shall cover all aspects of conformity – ie it shall list all the basic requirement documents relevant to the product.

Before issuing DoC, the manufacturer or a designated third party shall carry out the *Assessment of Conformity* (AoC).

Shall – shall not

In provisions and standards, these English words strictly indicate a duty or ban.
Shall means: must, has to, is obliged. – *Shall not* means: is not allowed, is forbidden, is banned.

Third party

There are normally two parties involved in a transaction: the seller and the buyer. Their interests tend to be different and sometimes conflicting. The seller wants to sell everything with maximum profits and with minimum guarantees – while the customer, on the other hand, wants to buy cheaply and with maximum guarantees. That is why – sometimes voluntarily and sometimes obligatorily under the provisions – a *third party* is used: a person or institution that enjoys the trust of both parties and is sufficiently qualified to make an independent professional assessment of whether the product is safe, manufactured according to the provisions, or meets some special requirement or parameter.

Examples of a third party may be an accredited testing laboratory or certification body, a notified body, a market surveillance authority or a court.

7.2. Abbreviations

DoC	EU Declaration of Conformity
EC, EEC	European Communities, European Economic Community (predecessors of the EU, until 2009)
EEE	Electrical and electronic equipment
EMC	Electromagnetic compatibility
EN	European Standard (issued by CEN)
ErP	Ecodesign (Energy-related products)
EU	European Union
LVD	Electrical safety of low-voltage electrical equipment (Low Voltage Devices)
MD	Machinery Directive
MDR	Medical Device Regulation
NANDO	New Approach Notified and Designated Organisations (EU information portal containing the New Approach provisions and competences of Notified and Designated Bodies)
ProCoP	Product Contact Point (official national advisory point for product provisions)
RED	Radio Equipment Directive
RoHS	Restriction of Hazardous Substances in EEE

7.3. Links

The second column indicates the language of the document.
An asterisk indicates that the document is available in the languages of all EU Member States.

Brochure on the New and Global Approach (Blue Guide)	*	https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules_en
Czech Accreditation Institute	EN	www.cai.cz/?page_id=12902&lang=en
Czech legislation	CZ	www.zakonyprolidi.cz
Czech Trade Inspection Authority (CTIA)	EN	https://www.coi.cz/en/
EMC Directive Handbook	EN	https://celectronics.com/pdf/EMC%20GUIDE%202018-03%20FINAL.pdf
EUR-lex (EU legislation)	*	https://eur-lex.europa.eu/homepage.html?locale=cs
Guide to the LVD Directive	EN	https://ec.europa.eu/docsroom/documents/31221
Harmonized standards to CE-related provisions	*	http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/
NANDO Database (CE-related provisions)	EN	http://ec.europa.eu/growth/tools-databases/nando/
PROduct COntact Points in all EU Member States	EN	https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list/
Regulations for ecodesign and energy labels	EN	https://ec.europa.eu/energy/topics/energy-efficiency/energy-efficient-products/list-regulations-product-groups-energy-efficient-products_en
RoHS Guide / FAQ	EN	https://www.rohsguide.com/ https://ec.europa.eu/environment/topics/waste-and-recycling/rohs-directive_en