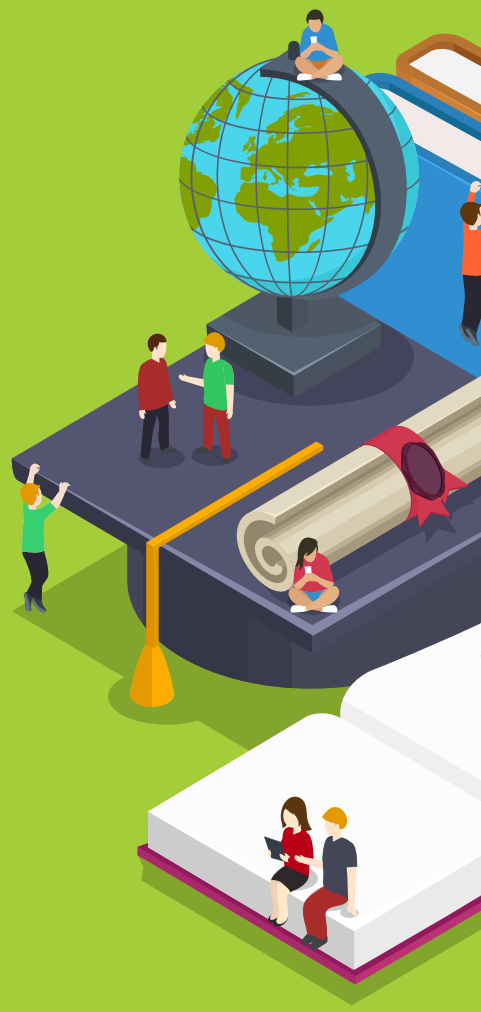
THE ULTIMATE GUIDE TO EUROPEAN CE DIRECTIVES AND REGULATIONS



Learn how to determine which Directives and Regulations apply to your product.

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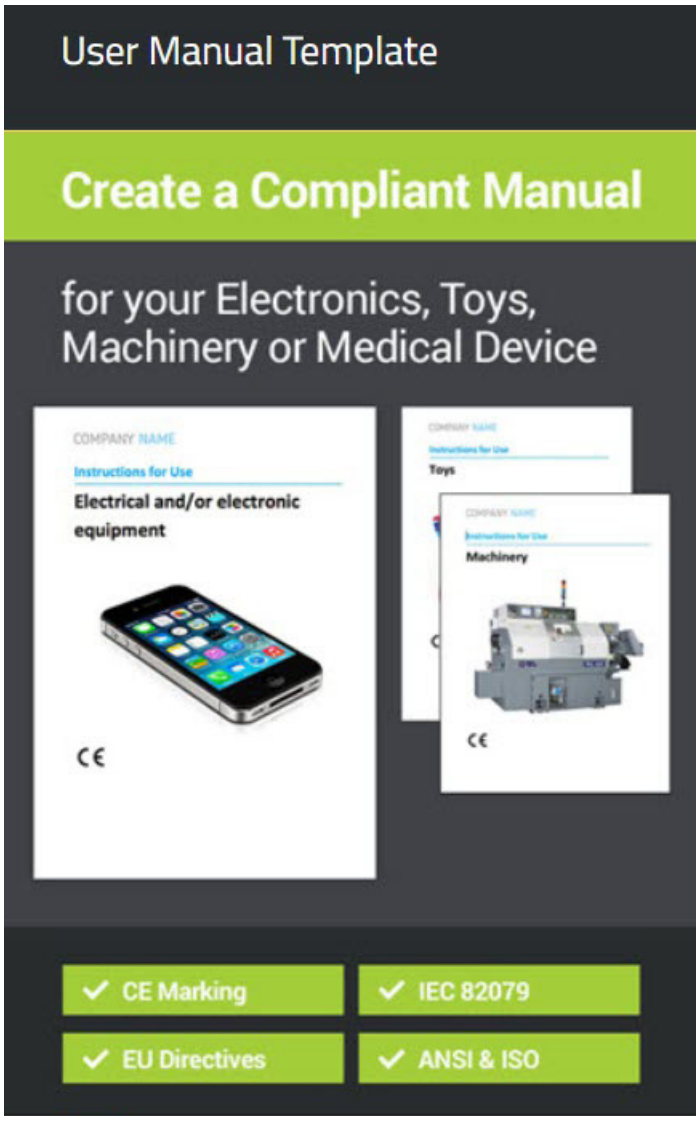

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Do you want to know how to get CE certification? Are you struggling with identifying which legislation applies to your product?

The CE marking process always consists of six steps. Step 1 is about identifying which CE Directives and Regulations apply to your product.

In this ebook I will show you exactly how you can determine yourself which Directives and Regulations apply to your product.

By following the steps that I describe in this post, you will be able to conduct the first step of the CE marking process yourself, without hiring an expensive CE consultant.

After all, in many cases, CE Marking is a **self certification** process.

What are CE Directives and Regulations

Many products that are being sold in the European Economic Area (EEA) require CE marking. The CE marking logo on a product means that the product:

- falls within the scope of CE marking;
- has had a conformity assessment procedure carried out;
- meets EU safety, health and environmental protection requirements.

The EU requirements are laid down in **CE Directives** and Regulations that cover different products or product sectors, such as toys, electrical equipment, machinery, medical devices, construction products and personal protective equipment.

There is a difference between Directives and Regulations.

Directives lay down certain results that must be achieved. However, **each Member State is free to decide how to translate directives into national laws.**

Regulations, on the other hand, have binding legal force throughout every Member State and enter into force on a set date in all the Member States.

Consult this CE mark database with an overview of all CE Directives and Regulations

How to Identify the Applicable CE Directives

Unfortunately, determining which CE marking directives and regulations apply to your product can be a daunting task. The European Commission does not provide a complete list of products for which CE marking applies, nor do they provide a full list of all CE marking directives and regulations.

The CE marking only applies to certain product groups or product aspects that are placed in the market, or put into service in the European Economic Area (EEA) and Iceland, Norway and Liechtenstein.

In order to determine the relevant CE marking directives for your product, you need to do the following:

1. make a shortlist of the CE directives that might apply to your product (see Step 1).
2. verify the directives and determine if they apply to your product by checking the scope and the definitions (see Step 2).

Step 1: Make a Shortlist of the CE Directives That Might Apply to Your Product

It is not up to you to determine IF you will use a certain directive. If your product falls within the scope of a directive, your product simply MUST meet the directive's requirements.

For example, if you are a manufacturer of 3D printers, the product falls within the scope of the Machinery Directive because it contains moving parts.

According to the Machinery Directive, machinery is, amongst other things, "an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application".

We had a client that sent us the following email:

We discussed that our 3D printers are covered by the Machinery Directive. I think we interpreted "covered" too strictly.

We have a new person responsible for compliance within our engineering team, and he's rightfully questioning our directives and process. It seems that the Machinery Directive is an option for 3D printers, but that the Low Voltage Directive also remains an option.

Our take is that the Machinery Directive is more for industrial-style equipment in which the primary risks are mechanical hazards, and that the Low Voltage Directive is better suited for smaller scale systems in which the primary risks are electrical.

We believe that we could possibly be covered by the Low Voltage Directive.

Remember: A directive is never an option, nor is any other directive better suited than the applicable directive.

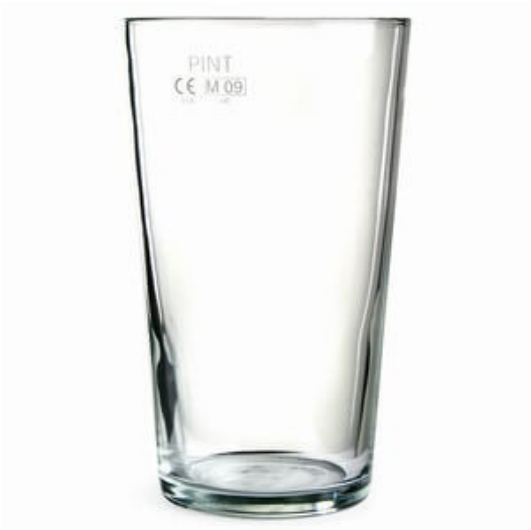
From the list below, mark all product groups that might apply to your product. If you have any doubts, mark it anyway. In the next step we are going to verify if the directives really apply to your product.

What products need CE marking:

- ☐ Toys
- ☐ Machinery
- ☐ Electrical /electronic equipment
- ☐ Personal protective equipment
- ☐ Radio equipment
- ☐ Medical devices
- ☐ Active implantable medical devices
- ☐ In vitro diagnostics
- ☐ Simple pressure vessels
- ☐ Gas appliances
- ☐ Lifts
- ☐ Recreational craft
- ☐ Equipment and protective systems for use in explosive atmospheres
- ☐ Non-automatic weighing instruments
- ☐ Cableways
- ☐ Construction products
- ☐ Explosives for civil use
- ☐ New hot water boilers
- ☐ Measuring Equipment
- ☐ Pressure equipment

The CE Marking is required only for products for which a CE marking directive or regulation has been adopted. If a CE Marking directive or regulation does NOT exist for your product, it is not allowed to mark your product with CE Marking.

The below example shows a pint glass. Because a pint glass is intended to hold either a British ("imperial") pint of 20 imperial fluid ounces (568 ml) or an American pint of 16 US fluid ounces (473 ml), the glass is a measuring device.



Step 2: Verify the CE Directives and determine whether they apply to your product

In order to know for sure if a directive applies to your product, you need to check the scope, definitions and exceptions of the directives.

I have made things easy for you! Below you will find the scope, definitions and exceptions of the most important directives.

CE Directive 2006/42/EC on Machinery

Scope of the Machinery Directive

This Directive applies to the following products:

a. machinery;
b. interchangeable equipment;
c. safety components;
d. lifting accessories;
e. chains, ropes and webbing;
f. removable mechanical transmission devices;
g. partly completed machinery.

Exceptions of the CE Directive for Machinery

The following are excluded from the scope of this Directive:

a. safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;
b. specific equipment for use in fairgrounds and/or amusement parks;
c. machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;
d. weapons, including firearms;
e. the following means of transport:
    - agricultural and forestry tractors for the risks covered by Directive 2003/37/EC, with the exclusion of machinery mounted on these vehicles,
    - motor vehicles and their trailers covered by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers, with the exclusion of machinery mounted on these vehicles,
    - vehicles covered by Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles, with the exclusion of machinery mounted on these vehicles,
    - motor vehicles exclusively intended for competition, and
    - means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport;

f. seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;
g. machinery specially designed and constructed for military or police purposes;
h. machinery specially designed and constructed for research purposes for temporary use in laboratories;
i. mine winding gear;
j. machinery intended to move performers during artistic performances;
k. electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits:
    - household appliances intended for domestic use;
    - audio and video equipment;
    - information technology equipment;
    - ordinary office machinery;
    - low-voltage switchgear and control gear;
    - electric motors.
l. the following types of high-voltage electrical equipment:
    - switchgear and control gear;
    - transformers.

Definitions of the Machinery Directive

The following definitions apply:

a. 'machinery' means:
    - an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of **linked parts or components, at least one of which moves**, and which are joined together for a specific application,
    - an assembly referred to in the first indent, missing only the components to connect it onsite or to sources of energy and motion,
    - an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,

- assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole,
- an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;

b. 'interchangeable equipment' means a device which, after putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;

c. 'safety component' means a component:
   - which serves to fulfil a safety function,
   - which is independently placed on the market,
   - the failure and/or malfunction of which endangers the safety of persons, and
   - which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function. An indicative list of safety components is set out in Annex V, which may be updated in accordance with Article 8(1)(a);

d. 'lifting accessory' means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories;

e. 'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;

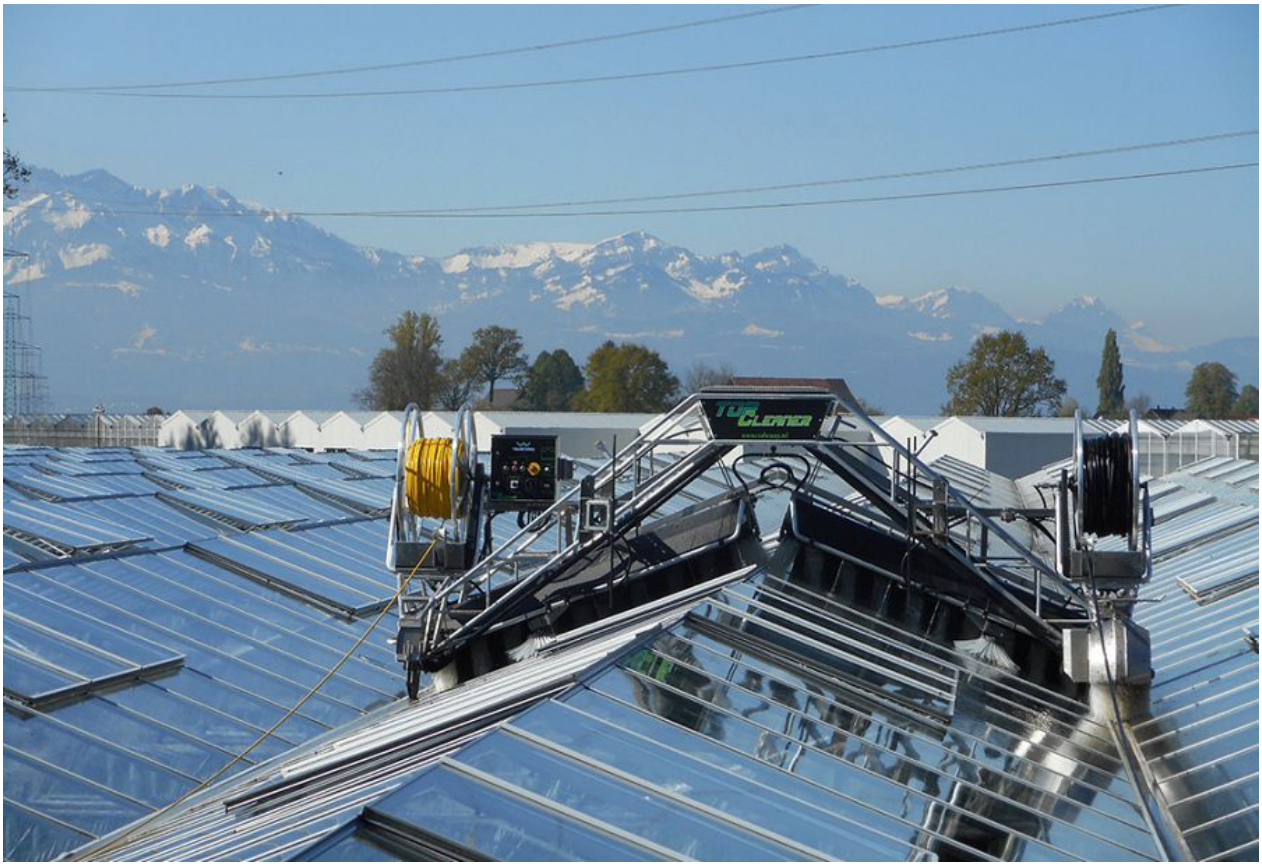
f. 'removable mechanical transmission device' means a removable component for transmitting power between self propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product;

g. 'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies.

Indicative List of the Safety Components (Annex V Machinery Directive)

1. Guards for removable mechanical transmission devices.
2. Protective devices designed to detect the presence of persons.
3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex IV.
4. Logic units to ensure safety functions.
5. Valves with additional means for failure detection intended for the control of dangerous movements on machinery.
6. Extraction systems for machinery emissions.
7. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.
8. Monitoring devices for loading and movement control in lifting machinery.
9. Restraint systems to keep persons on their seats.
10. Emergency stop devices.
11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.
12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex I.
13. Systems and devices to reduce the emission of noise and vibrations.
14. Roll-over protective structures (ROPS).
15. Falling-object protective structures (FOPS).
16. Two-hand control devices.
17. Components for machinery designed for lifting and/or lowering persons between different landings and included in the following list:
    a. devices for locking landing doors;
    b. devices to prevent the load-carrying unit from falling or unchecked upwards movement;
    c. overspeed limitation devices;
    d. energy-accumulating shock absorbers,
        i. non-linear, or
        ii. with damping of the return movement;
    e. energy-dissipating shock absorbers;

f. safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;
g. electric safety devices in the form of safety switches containing electronic components.



Regulation (EU) No 305/2011 on Construction Products

Scope of the (EU) 305/2011 Regulation

This Regulation applies to Construction Products.

Definitions of the Regulation on Construction Products

The following definitions apply:

- 'construction product' means any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works;
- 'kit' means a construction product placed on the market by a single manufacturer as a set of at least two separate components that need to be put together to be incorporated in the construction works;
- 'construction works' means buildings and civil engineering works.

Regulation (EU) 2017/745 on Medical Devices

Scope of the Medical Devices Regulation

This Regulation applies to the following products:

1. medical devices for human use and accessories for such devices in the Union.
2. clinical investigations concerning such medical devices and accessories conducted in the Union.
3. groups of products without an intended medical purpose that are listed in Annex XVI, taking into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology:
    a. contact lenses or other items intended to be introduced into or onto the eye;
    b. products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings;
    c. substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing;
    d. equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty;
    e. high intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment;
    f. equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

Exceptions of the Medical Devices Regulation

The following are excluded from the scope of this Directive:

a. in vitro diagnostic medical devices covered by Regulation (EU) 2017/746;

b. medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC. In deciding whether a product falls under Directive 2001/83/EC or under this Regulation, particular account shall be taken of the principal mode of action of the product;
c. advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;
d. human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or put into service, such blood products, plasma or cells, except for devices referred to in paragraph 8 of this Article;
e. cosmetic products covered by Regulation (EC) No 1223/2009;
f. transplants, tissues or cells of animal origin, or their derivatives, or products containing or consisting of them; however this Regulation does apply to devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or are rendered non-viable;
g. transplants, tissues or cells of human origin, or their derivatives, covered by Directive 2004/23/EC, or products containing or consisting of them; however this Regulation does apply to devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;
h. products, other than those referred to in points (d), (f) and (g), that contain or consist of viable biological material or viable organisms, including living microorganisms, bacteria, fungi or viruses in order to achieve or support the intended purpose of the product;
i. food covered by Regulation (EC) No 178/2002.

Definitions of the Medical Devices Regulation

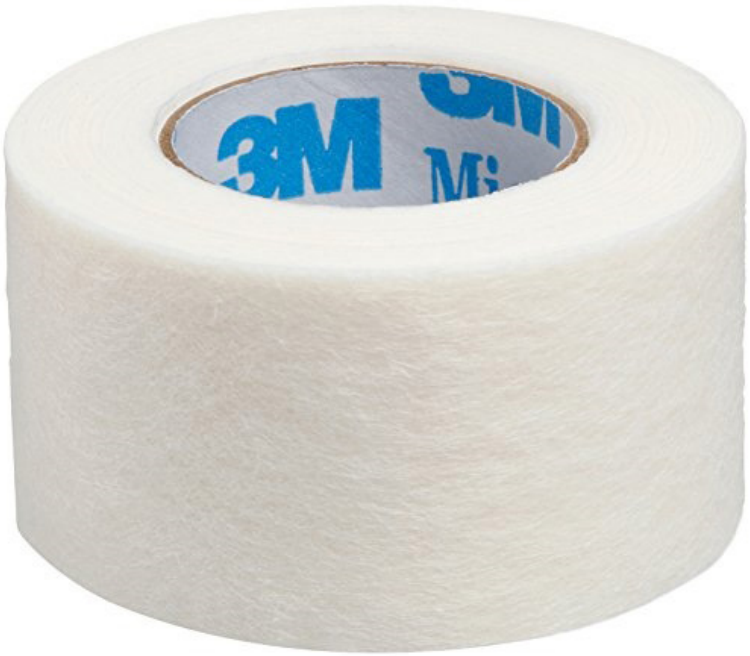
The following definitions apply:

a. 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
    - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
    - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
    - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;

- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

  The following products shall also be deemed to be medical devices:
- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

b. 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).



Also, sport tape is considered a medical device.

Regulation (EU) 2016/425 on Personal Protective Equipment

Scope of the Regulation on Personal Protective Equipment

This Directive applies to personal protective equipment (PPE).

Exceptions of the Regulation on Personal Protective Equipment

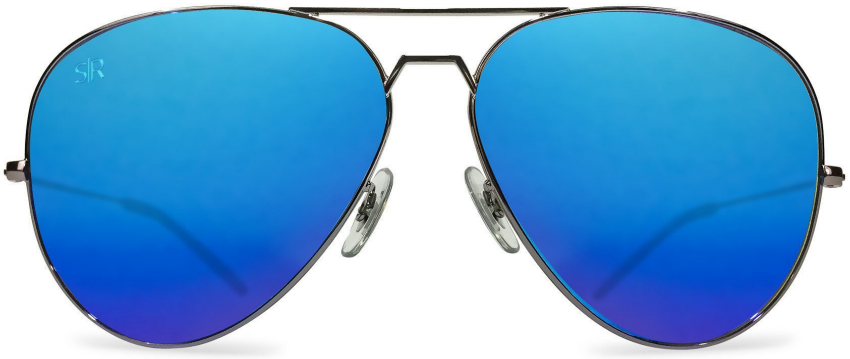
The following are excluded from the scope of this Directive:

a. PPE specifically designed for use by the armed forces or in the maintenance of law and order;
b. PPE designed to be used for self-defence, with the exception of PPE intended for sporting activities;
c. designed for private use to protect against:
    i. atmospheric conditions that are not of an extreme nature,
    ii. damp and water during dishwashing;
d. for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;
e. for head, face or eye protection of users, that is covered by Regulation No 22 of the United Nations Economic Commission for Europe on uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motorcycles and mopeds.

Definitions of the Regulation on Personal Protective Equipment

The following definitions apply:

- 'personal protective equipment' (PPE) means:
    - equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety;
    - interchangeable components for equipment referred to in point (a) which are essential for its protective function;
    - connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use.



Sunglasses protect the eyes against sun light and thus are considered to be personal protective equipment.

CE Directive 2009/48/EC on Toy Safety

Scope of the Toy Safety Directive

This Directive applies to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age.

Exceptions of the Toy Safety Directive

The following are excluded from the scope of this Directive:

a. playground equipment intended for public use;
b. automatic playing machines, whether coin operated or not, intended for public use;
c. toy vehicles equipped with combustion engines;
d. toy steam engines; and
e. slings and catapults;
f. products listed in Annex I:
    a. decorative objects for festivities and celebrations;
    b. products for collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years of age and above. Examples of this category are:
        i. detailed and faithful scale models;
        ii. kits for the assembly of detailed scale models;
        iii. folk dolls and decorative dolls and other similar articles;
        iv. historical replicas of toys; and
        v. reproductions of real fire arms.
    c. sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass of more than 20 kg;
    d. bicycles with a maximum saddle height of more than 435 mm, measured as the vertical distance from the ground to the top of the seat surface, with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark;
    e. scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways;
    f. electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or the pavement thereof;

g. aquatic equipment intended to be used in deep water, and swimming learning devices for children, such as swim seats and swimming aids;
h. puzzles with more than 500 pieces;
i. guns and pistols using compressed gas, with the exception of water guns and water pistols, and bows for archery over 120 cm long;
j. fireworks, including percussion caps which are not specifically designed for toys;
k. products and games using sharp-pointed missiles, such as sets of darts with metallic points;;
l. functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts which are sold exclusively for teaching purposes under adult supervision;
m. products intended for use for educational purposes in schools and other pedagogical contexts under the surveillance of an adult instructor, such as science equipment;
n. electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for and targeted at children and have a play value on their own, such as specially designed personal computers, keyboards, joy sticks or steering wheels;
o. interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CDs;
p. 'babies' soothers;
q. child-appealing luminaires;
r. electrical transformers for toys;
s. fashion accessories for children which are not for use in play.

CE Directive 2014/30/EU relating to Electromagnetic Compatibility

Scope of the EMC Directive

This Directive applies to equipment/any apparatus or fixed installation made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance.

Exceptions of the EMC Directive

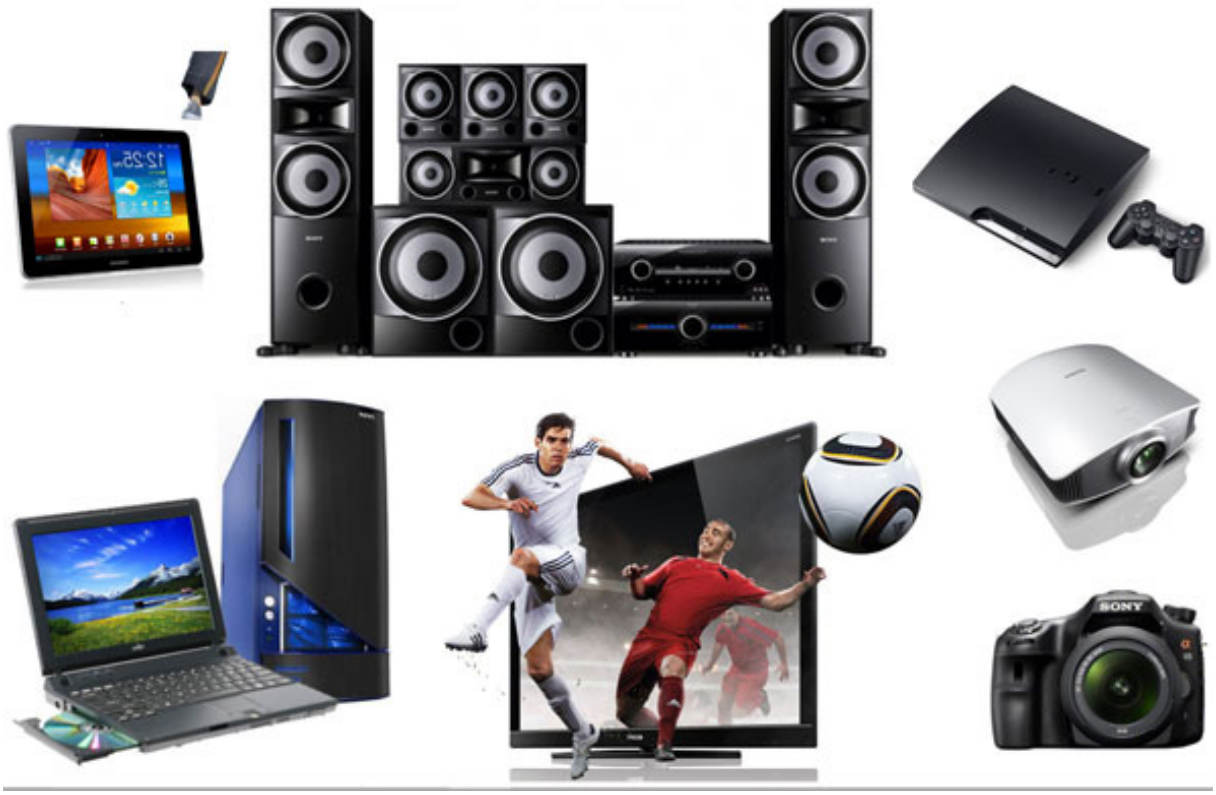
The following are excluded from the scope of this Directive:

a. equipment covered by Directive 1999/5/EC;
b. aeronautical products, parts and appliances as referred to in Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (9);
c. radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution of the International Telecommunication Union and the Convention of the International Telecommunication Union (10), unless the equipment is made available on the market. ***NOTICE*** Kits of components to be assembled by radio amateurs and equipment made available on the market and modified by and for the use of radio amateurs are not regarded as equipment made available on the market;
d. equipment, the inherent nature of the physical characteristics of which, is such that:
    a. it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and
    b. it operates without unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use;
e. custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

Definitions of the EMC Directive

The following definitions apply:

a. 'equipment' means any apparatus or fixed installation;
b. 'apparatus' means any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;
c. 'fixed installation' means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location;
d. 'electromagnetic compatibility' means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment;
e. 'electromagnetic disturbance' means any electromagnetic phenomenon which may degrade the performance of equipment; an electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself.



Consumer electronics always need to comply with the EMC Directive.

CE Directive 2014/35/EU relating to the making available on the market of electrical equipment designed for use within certain voltage limits (Low Voltage Directive)

Scope of the Low Voltage Directive

This Directive applies to the electrical equipment designed for use with a voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current.

Exceptions of the Low Voltage Directive

The following are excluded from the scope of this Directive:

a. electrical equipment for use in an explosive atmosphere;
b. electrical equipment for radiology and medical purposes;
c. electrical parts for goods and passenger lifts;
d. electricity meters;
e. plugs and socket outlets for domestic use;
f. electric fence controllers;
g. radio-electrical interference;
h. specialised electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate;
i. custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes;
j. radio equipment covered by Directive 2014/53/EU.

CE Directive 2014/53/EU relating to Radio Equipment

Scope of the Radio Equipment Directive

This Directive applies to Radio Equipment.

Exceptions of the Radio Equipment Directive

The following are excluded from the scope of this Directive:

a. radio equipment used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union (ITU) Radio Regulations, unless the equipment is made available on the market. The following shall be regarded as not being made available on the market:
    i. radio kits for assembly and use by radio amateurs;
    ii. radio equipment modified by and for the use of radio amateurs;
    iii. equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio.
b. marine equipment falling within the scope of Council Directive 96/98/EC (1);
c. airborne products, parts and appliances falling within the scope of Article 3 of Regulation (EC) No 216/2008 of the European Parliament and of the Council (2);
d. custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes;
e. radio equipment exclusively used for activities concerning public security, defence, state security, including the economic well-being of the State in the case of activities pertaining to state security matters, and the activities of the State in the area of criminal law.

Definitions of the Radio Equipment Directive

The following definitions apply:

- 'radio equipment' means an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as an antenna, so as to intentionally emit and/or receive radio

waves for the purpose of radio communication and/or radiodetermination;

- ‘radio communication’ means communication by means of radio waves;
- ‘radiodetermination’ means the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves;
- ‘radio waves’ means electromagnetic waves of frequencies lower than 3,000 GHz, propagated in space without artificial guide.

CE Directive 2011/65/EU on the restrictions of the use of certain hazardous substances in electrical equipment

Scope of the RoHS Directive

This Directive applies to electrical and electronic equipment (EEE) falling within the following categories:

1. large household appliances;
2. small household appliances;
3. IT and telecommunications equipment;
4. consumer equipment;
5. lighting equipment;
6. electrical and electronic tools;
7. toys, leisure and sports equipment;
8. medical devices;
9. monitoring and control instruments including industrial monitoring and control instruments;
10. automatic dispensers;
11. other EEE not covered by any of the categories above.

Exceptions of the RoHS Directive

The following are excluded from the scope of this Directive:

a. equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;
b. equipment designed to be sent into space;
c. equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;
d. large-scale stationary industrial tools;

e. large-scale fixed installations;
f. means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;
g. non-road mobile machinery made available exclusively for professional use;
h. active implantable medical devices;
i. photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;
j. equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

CE Directive 2009/125/EC on Energy-Related Products

Scope of the Directive on Energy Related Products

This Directive applies to energy-related products.

Exceptions of the Directive on Energy Related Products

The following are excluded from the scope of this Directive:

- means of transport for persons or goods.

Definitions of the Directive on Energy Related Products

The following definitions apply:

- 'Energy-related product', (a 'product'), means any good that has an impact on energy consumption during use which is placed on the market and/or put into service, and includes parts intended to be incorporated into energy-related products covered by this Directive which are placed on the market and/or put into service as individual parts for end-users and of which the environmental performance can be assessed independently.

CE Directive 2000/14/EC on Noise Equipment for use outdoors

Scope of the Noise Equipment Directive

This Directive applies equipment for use outdoors listed in Articles 12 and 13 and defined in Annex I of the Directive.

NOTICE This Directive only covers equipment that is placed on the market or put into service as an entire unit suitable for the intended use. Non-powered attachments that are separately placed on the market or put into service shall be excluded, except for hand-held concrete-breakers and picks and for hydraulic hammers.

Exceptions of the Noise Equipment Directive

The following are excluded from the scope of this Directive:

- all equipment primarily intended for the transport of goods or persons by road or rail or by air or on waterways;
- equipment specially designed and constructed for military and police purposes and for emergency services.

Definitions of the Noise Equipment Directive

The following definitions apply:

- "equipment for use outdoors" means all machinery defined in Article 1(2) of Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery(17) which is either self-propelled or can be moved and which, irrespective of the driving element(s), is intended to be used, according to its type, in the open air and which contributes to environmental noise exposure. The use of equipment in an ambience where the transmission of sound is not or not significantly affected (for instance under tents, under roofs for protection against rain or in the shell of houses) is regarded as use in the open air. It also means non-powered equipment for industrial or environmental applications which is intended, according to its type, to be used outdoors and which contributes to environmental noise exposure. All these types of equipment are hereinafter referred to as "equipment."

CE Directive 2000/9/EC on Cableway Installations

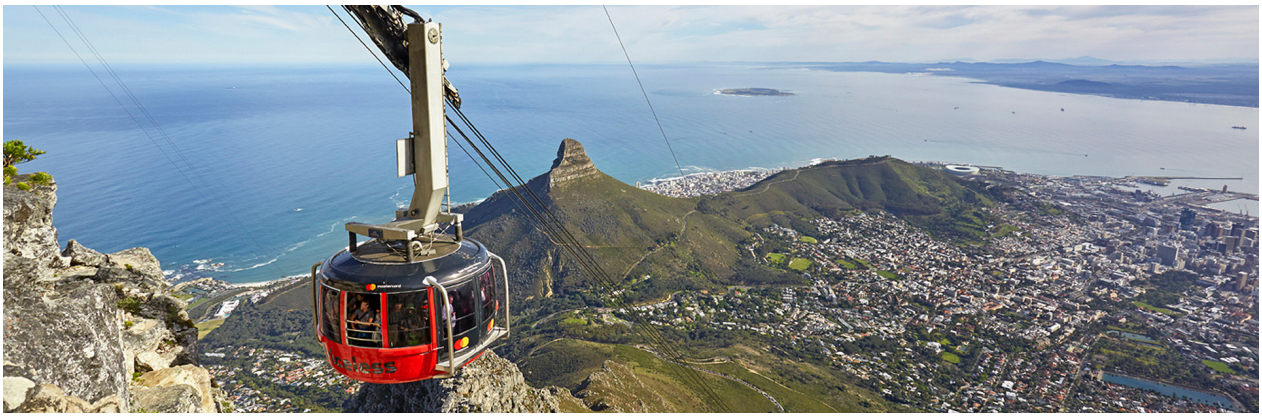
Scope of the Cableway installations Directive

This Directive applies to cableway installations designed to carry persons. This Directive shall apply to installations built and put into service, as from its entry into force, and subsystems and safety components placed on the market, as from its entry into force.

Definitions of the Cableway installations Directive

The following definitions apply:

- "cableway installations designed to carry persons" shall mean installations made up of several components, designed, manufactured, assembled and put into service with the object of carrying persons;
- "installation" shall mean the whole on-site system, consisting of infrastructure and the subsystems listed in Annex I where infrastructure specially designed for each installation and constructed on site shall mean the layout, system data, station structures and structures along the line, which are needed for the construction and the operation of the installation, including the foundations;
- "safety component" shall mean any basic component, set of components, subassembly or complete assembly of equipment and any device incorporated in the installation for the purpose of ensuring a safety function and identified by the safety analysis, the failure of which endangers the safety or health of persons, be they users, operating personnel or third parties.



CE Directive 2009/142/EC on Gas Appliances

Scope of the Gas Appliance Directive

This Directive applies to appliances and fittings.

Exceptions of the Gas Appliance Directive

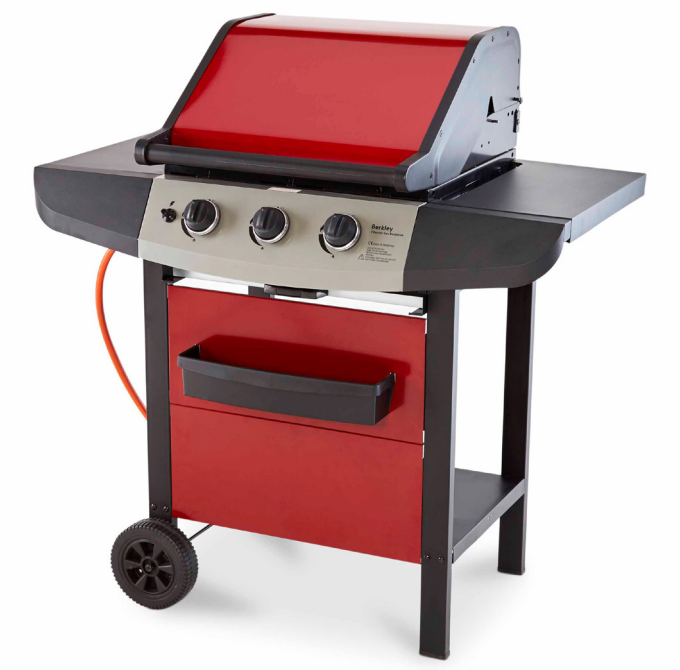
The following are excluded from the scope of this Directive:

- appliances specifically designed for use in industrial processes carried out on industrial premises.

Definitions of the Gas Appliance Directive

The following definitions apply:

- 'appliances' means appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing and having, where applicable, a normal water temperature not exceeding 105 °C. Forced draught burners and heating bodies to be equipped with such burners shall also be considered as appliances;
- 'fittings' means safety devices, controlling devices or regulating devices and sub-assemblies, other than forced draught burners and heating bodies to be equipped with such burners, separately marketed for trade use and designed to be incorporated into an appliance burning gaseous fuel or assembled to constitute such an appliance.



CE Directive 2013/29/EU on Pyrotechnic Articles

Scope of the Pyrotechnic Articles Directive

This Directive applies to pyrotechnic articles.

Exceptions of the Pyrotechnic Articles Directive

The following are excluded from the scope of this Directive:

- pyrotechnic articles intended for non-commercial use, in accordance with national law, by the armed forces, the police or fire departments;
- equipment falling within the scope of Directive 96/98/EC;
- pyrotechnic articles intended for use in the aerospace industry;
- percussion caps intended specifically for toys falling within the scope of Directive 2009/48/EC;
- explosives falling within the scope of Directive 93/15/EEC;
- ammunition;
- fireworks which are built by a manufacturer for his own use and approved for use exclusively on its territory by the Member State in which the manufacturer is established, and which remain on the territory of that Member State.

Definitions of the Pyrotechnic Articles Directive

The following definitions apply:

- 'pyrotechnic article' means any article containing explosive substances or an explosive mixture of substances designed to produce heat, light, sound, gas or smoke or a combination of such effects through self-sustained exothermic chemical reactions.

CE Directive 92/42/EEC on Hot Water Boilers

Scope of the Hot Water Boiler Directive

This Directive applies new hot-water boilers fired by liquid or gaseous fuels with a rated output of no less than 4 kW and no more than 400 kW.

Exceptions of the Hot Water Boiler Directive

The following are excluded from the scope of this Directive:

- hot-water boilers capable of being fired by different fuels including solid fuels;
- equipment for the instantaneous preparation of hot water;
- boilers designed to be fired by fuels the properties of which differ appreciably from the properties of the liquid and gaseous fuels commonly marketed (industrial waste gas, biogas, etc);
- cookers and appliances designed mainly to heat the premises in which they are installed and, as a subsidiary function, to supply hot water for central heating and sanitary hot water;
- appliances with rated outputs of less than 6 kW using gravity circulation and designed solely for the production of stored sanitary hot water;
- boilers manufactured on a one-off basis.

Definitions of the Hot Water Boiler Directive

The following definitions apply:

- boiler: the combined boiler body-burner unit, designed to transmit to water the heat released from burning.

CE Directive 2014/28/EU on Explosives for civil uses

Scope of the Explosives for Civil Use Directive

This Directive applies to explosives for civil uses.

Exceptions of the Explosives for Civil Use Directive

The following are excluded from the scope of this Directive:

a. explosives, including ammunition, intended for use, in accordance with national law, by the armed forces or the police;
b. pyrotechnic articles falling within the scope of Directive 2013/29/EU;
c. ammunition, save as provided for in Articles 12, 13 and 14.

NOTICE Annex I of the Directive contains a non-exhaustive list of pyrotechnic articles and ammunition.

Definitions of the Explosives for Civil Use Directive

The following definitions apply:

- 'explosives' means the materials and articles considered to be explosives in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations;
- 'ammunition' means projectiles with or without propelling charges and blank ammunition used in portable firearms, other guns and artillery.

CE Directive 2014/29/EU on Pressure Vessels

Scope of the Pressure Vessel Directive

This Directive applies to simple pressure vessels ('vessels') manufactured in series with the following characteristics:

- the vessels are welded, intended to be subjected to an internal gauge pressure greater than 0.5 bar and to contain air or nitrogen, and are not intended to be fired;
- the parts and assemblies contributing to the strength of the vessel under pressure are made either of non-alloy quality steel or of non-alloy aluminium or non-age hardening aluminium alloys;
- the vessel is made of either of the following elements:
  - a cylindrical part of circular cross-section closed by outwardly dished and/or flat ends which revolve around the same axis as the cylindrical part;
  - two dished ends revolving around the same axis;
- the maximum working pressure of the vessel does not exceed 30 bar and the product of that pressure and the capacity of the vessel (PS × V) does not exceed 10 000 bar.L;
- the minimum working temperature is no lower than – 50 °C and the maximum working temperature is not higher than 300 °C for steel and 100 °C for aluminium or aluminium alloy vessels.

Exceptions of the Pressure Vessel Directive

The following are excluded from the scope of this Directive:

1. vessels specifically designed for nuclear use, failure of which may cause an emission of radioactivity;
2. vessels specifically intended for installation in or the propulsion of ships and aircraft;
3. fire extinguishers.

CE Directive 2014/31/EU on Weighing Instruments

Scope of the Weighing Instruments Directive

This Directive applies to all non-automatic weighing instruments.

Exceptions of the Weighing Instruments Directive

The following categories of use of non-automatic weighing instruments are excluded from the scope of this Directive:

a. determination of mass for commercial transactions;
b. determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;
c. determination of mass for the application of laws or regulations or for an expert opinion given in court proceedings;
d. determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;
e. determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories;
f. determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of pre-packages;
g. all applications other than those listed in points (a) to (f).

Definitions of the Weighing Instruments Directive

The following definitions apply:

- 'weighing instrument' means a measuring instrument serving to determine the mass of a body by using the action of gravity on that body. A weighing instrument may also serve to determine other mass-related magnitudes, quantities, parameters or characteristics;
- 'non-automatic weighing instrument' or 'instrument' means a weighing instrument requiring the intervention of an operator during weighing.

CE Directive 2014/32/EU on Measuring Instruments

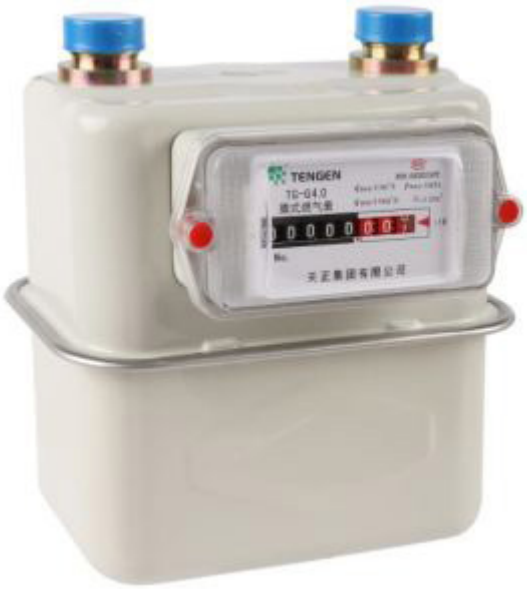
Scope of the Measuring Instrument Directive

This Directive applies to the measuring instruments defined in the instrument-specific Annexes III to XII of the Directive concerning water meters (MI-001), gas meters and volume conversion devices (MI-002), active electrical energy meters (MI-003), thermal energy meters (MI-004), measuring systems for continuous and dynamic measurement of quantities of liquids other than water (MI-005), automatic weighing instruments (MI-006), taximeters (MI-007), material measures (MI-008), dimensional measuring instruments (MI-009) and exhaust gas analysers (MI-010).

Definitions of the Measuring Instrument Directive

The following definitions apply:

- 'measuring instrument' means any device or system with a measurement function that is covered by the Scope.



CE Directive 2014/33/EU on Lifts

Scope of the Lift Directive

This Directive applies to lifts permanently serving buildings and constructions and intended for the transport of:

a. persons;
b. persons and goods;
c. goods alone if the carrier is accessible, that is to say a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier.

This Directive shall also apply to the following safety components for lifts:

1. devices for locking landing doors;
2. devices to prevent falls referred to in point 3.2 of Annex I to prevent the car from falling or uncontrolled movements;
3. overspeed limitation devices;
4. (a) energy-accumulating buffers:
   i. non-linear, or
   ii. with damping of the return movement;
   (b) energy-dissipating buffers;
5. safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;
6. electric safety devices in the form of safety circuits containing electronic components.

Exceptions of the Lift Directive

The following are excluded from the scope of this Directive:

a. lifting appliances whose speed is not greater than 0.15 m/s;
b. construction site hoists;
c. cableways, including funicular railways;
d. lifts specially designed and constructed for military or police purposes;
e. lifting appliances from which work can be carried out;
f. mine winding gear;

g. lifting appliances intended for lifting performers during artistic performances;
h. lifting appliances fitted in means of transport;
i. lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery;
j. rack and pinion trains;
k. escalators and mechanical walkways.

Definitions of the Lift Directive

The following definitions apply:

- 'lift' means a lifting appliance serving specific levels, having a carrier moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal, or a lifting appliance moving along a fixed course even where it does not move along rigid guides;
- 'carrier' means a part of the lift by which persons and/or goods are supported in order to be lifted or lowered.

CE Directive 2014/34/EU relating to equipment and protective systems for use in potentially explosive atmospheres

Scope of the ATEX Directive

This Directive applies to the following products:

a. equipment and protective systems intended for use in potentially explosive atmospheres;
b. safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion;
c. components intended to be incorporated into equipment and protective systems referred to in point (a).

Exceptions of the ATEX Directive

The following are excluded from the scope of this Directive:

a. medical devices intended for use in a medical environment;
b. equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances;
c. equipment intended for use in domestic and noncommercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas;
d. personal protective equipment covered by Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment;
e. seagoing vessels and mobile offshore units together with equipment on board such vessels or units;
f. means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, by public road or rail networks or by water. Vehicles intended for use in a potentially explosive atmosphere

shall not be excluded from the scope of this Directive;

g. the equipment covered by point (b) of Article 346(1) of the Treaty on the Functioning of the European Union.

Definitions of the ATEX Directive

The following definitions apply:

- 'equipment' means machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy and/or the processing of material and which are capable of causing an explosion through their own potential sources of ignition.

CE Directive 90/385/EEC on Active Implantable Medical Devices

Scope of the Active Implantable Medical Devices Directive

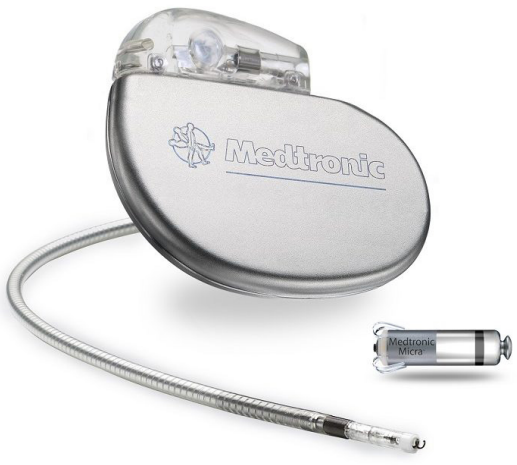
This Directive applies to active implantable medical devices.

Definitions of the Active Implantable Medical Devices Directive

The following definitions apply:

- 'medical device' means any instrument, apparatus, appliance , material or other article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease or injury,
  - investigation, replacement or modification of the anatomy or of a physiological process,
  - control of conception,

  and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means;
- 'active medical device' means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;
- 'active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body, or by medical intervention into a natural orifice, and which is intended to remain after the procedure.



CE Directive 2013/53/EU on Recreational Craft

Scope of the Recreational Craft Directive

This Directive applies to the following products:

a. recreational craft and partly completed recreational craft;
b. personal watercraft and partly completed personal watercraft;
c. components listed in Annex II when placed on the Union market separately, hereinafter referred to as 'components';
d. propulsion engines which are installed or specifically intended for installation on or in watercraft;
e. propulsion engines installed on or in watercraft that are subject to a major engine modification;
f. watercraft that are subject to major craft conversion.

Exceptions of the Recreational Craft Directive

The following are excluded from the scope of this Directive:

a. with regard to the design and construction requirements set out in Part A of Annex I:
    i. watercraft intended solely for racing, including rowing racing boats and training rowing boats, labelled as such by the manufacturer;
    ii. canoes and kayaks designed to be propelled solely by human power, gondolas and pedalos;
    iii. surfboards designed solely to be propelled by wind and to be operated by a person or persons standing;
    iv. surfboards;
    v. original historical watercraft and individual replicas thereof designed before 1950, built predominantly with the original materials and labelled as such by the manufacturer;
    vi. experimental watercraft, provided that they are not placed on the Union market;
    vii. watercraft built for own use, provided that they are not subsequently placed on the Union market during a period of five years from the putting into service of the watercraft;

viii. watercraft specifically intended to be crewed and to carry passengers for commercial purposes, without prejudice to paragraph 3, regardless of the number of passengers;

ix. submersibles;

x. air cushion vehicles;

xi. hydrofoils;

xii. external combustion steam powered watercraft, fuelled by coal, coke, wood, oil or gas;

xiii. amphibious vehicles, i.e. wheeled or track-laying motor vehicles, which are able to operate both on water and on solid land.

b. with regard to exhaust emission requirements set out in Part B of Annex I:

i. propulsion engines installed or specifically intended for installation on the following products:

- watercraft intended solely for racing and labelled as such by the manufacturer;
- experimental watercraft, provided that they are not placed on the Union market;
- watercraft specifically intended to be crewed and to carry passengers for commercial purposes, without prejudice to paragraph 3, regardless of the number of passengers;
- submersibles;
- air cushion vehicles;
- hydrofoils;
- amphibious vehicles, i.e. wheeled or track-laying motor vehicles, which are able to operate both on water and on solid land.

ii. original and individual replicas of historical propulsion engines, which are based on a pre-1950 design, not produced in series and fitted on watercraft referred to in points (v) or (vii) of point (a);

iii. propulsion engines built for own use provided that they are not subsequently placed on the Union market during a period of five years from the putting into service of the watercraft;

c. with regard to noise emission requirements referred to in Part C of Annex I:

i. all watercraft referred to in point (b);

ii. watercraft built for own use, provided that they are not subsequently placed on

the Union market during a period of five years from the putting into service of the watercraft.

Definitions of the Recreational Craft Directive

The following definitions apply:

- 'watercraft' means any recreational craft or personal watercraft;
- 'recreational craft' means any watercraft of any type, excluding personal watercraft, intended for sports and leisure purposes of hull length from 2.5 m to 24 m, regardless of the means of propulsion.

CE Directive 2014/68/EU on Pressure Equipment

Scope of the Pressure Equipment Directive

This Directive applies to pressure equipment and assemblies with a maximum allowable pressure PS greater than 0,5 bar.

Exceptions of the Pressure Equipment Directive

The following are excluded from the scope of this Directive:

a. pipelines comprising piping or a system of piping designed for the conveyance of any fluid or substance to or from an installation (onshore or offshore) starting from and including the last isolation device located within the confines of the installation, including all the annexed equipment designed specifically for pipelines; this exclusion shall not apply to standard pressure equipment such as may be found in pressure reduction stations or compression stations;
b. networks for the supply, distribution and discharge of water and associated equipment and headraces, such as penstocks, pressure tunnels, pressure shafts for hydroelectric installations and their related specific accessories;
c. simple pressure vessels covered by Directive 2014/29/EU of the European Parliament and of the Council (13);
d. aerosol dispensers covered by Council Directive 75/324/EEC (14);
e. equipment intended for the functioning of vehicles defined by the following legal acts:
    i. Directive 2007/46/EC of the European Parliament and of the Council (15);
    ii. Regulation (EU) No 167/2013 of the European Parliament and of the Council (16);
    iii. Regulation (EU) No 168/2013 of the European Parliament and of the Council (17);
f. equipment classified as no higher than category I under Article 13 of this Directive and covered by one of the following Directives:
    i. Directive 2006/42/EC of the European Parliament and of the Council (18);
    ii. Directive 2014/33/EU of the European Parliament and of the Council (19);
    iii. Directive 2014/35/EU of the European Parliament and of the Council (20);
    iv. Council Directive 93/42/EEC (21);
    v. Directive 2009/142/EC of the European Parliament and of the Council (22);

vi. Directive 2014/34/EU of the European Parliament and of the Council (23);

g. equipment covered by point (b) of Article 346(1) TFEU;

h. items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;

i. well-control equipment used in the petroleum, gas or geothermal exploration and extraction industry and in underground storage which is intended to contain and/or control well pressure; this shall comprise the wellhead (Christmas tree), the blow out preventers (BOP), the piping manifolds and all their equipment upstream;

j. equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor; such equipment may include:
   i. engines, including turbines and internal combustion engines;
   ii. steam engines, gas/steam turbines, turbo-generators, compressors, pumps and actuating devices;

k. blast furnaces, including the furnace cooling system, hot-blast recuperators, dust extractors and blast-furnace exhaust-gas scrubbers and direct reducing cupolas, including the furnace cooling, gas converters and pans for melting, re-melting, de-gassing and casting of steel, iron and non-ferrous metals;

l. enclosures for high-voltage electrical equipment such as switchgear, control gear, transformers, and rotating machines;

m. pressurised pipes for the containment of transmission systems, e.g. for electrical power and telephone cables;

n. ships, rockets, aircraft and mobile offshore units, as well as equipment specifically intended for installation on board or the propulsion thereof;

o. pressure equipment consisting of a flexible casing, e.g. tyres, air cushions, balls used for play, inflatable craft, and other similar pressure equipment;

p. exhaust and inlet silencers;

q. bottles or cans for carbonated drinks for final consumption;

r. vessels designed for the transport and distribution of drinks having a PS·V of not more than 500 bar·L and a maximum allowable pressure not exceeding 7 bar;

s. equipment covered by Directive 2008/68/EC and Directive 2010/35/EU and

equipment covered by the International Maritime Dangerous Goods Code and the Convention on International Civil Aviation;

t. radiators and pipes in warm water heating systems;

u. vessels designed to contain liquids with a gas pressure above the liquid of not more than 0,5 bar.

Definitions of the Pressure Equipment Directive

The following definitions apply:

- 'pressure equipment' means vessels, piping, safety accessories and pressure accessories, including, where applicable, elements attached to pressurised parts, such as flanges, nozzles, couplings, supports, lifting lugs.

CE Directive 98/79/EC on in vitro diagnostic medical devices

Scope of the In Vitro MD Directive

This Directive applies to in vitro diagnostic medical devices and their accessories.

Definitions of the In Vitro MD Directive

The following definitions apply:

- 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,
  - investigation, replacement or modification of the anatomy or of a physiological process,
  - control of conception,

  and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;
- 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:
  - concerning a physiological or pathological state, or
  - concerning a congenital abnormality, or
  - to determine the safety and compatibility with potential recipients, or
  - to monitor therapeutic measures.

Specimen receptacles are considered to be in vitro diagnostic medical devices. ‘Specimen receptacles’ are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

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