PLENARY SPEAK

LEGAL REQUIREMENTS OF HYDRAULIC POWER UNITS

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With the growing complexity of modern machinery and in order to ensure their safe and reliable operation, a lot of legal directives, regulations and standards have been published throughout the world. Mechanical engineers often struggle which have to be followed and when. This article focuses on the legal requirements which are applicable to hydraulic power units and their components in the European Single Market. In European Union the fundamental mandatory directive is Machinery Directive (2006/42/EC) which promotes the free movement of machinery within the single market and guarantees a high level of protection for EU workers and citizens. Which part of Machinery Directive is important for hydraulic power units and which other directives also apply will be described on the following pages. (This article was partially prepared before the new Machinery Regulation (Regulation (EU) 2023/1230) was published).

Keywords:
hydraulics, European directives, risk assessment, declarations, documentation, harmonized standards

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1 Introduction

There are a number of different regulations worldwide that have to be followed. Which of them are applicable is mainly defined by the location where the machine will be used at. As there are too many regulations available this article will focus on the regulations that are applicable when a machine will used in the European Union (EU).

The basic steps when determining which regulations are applicable for our product the following steps are recommended [1]:

1. **Product Classification:** Begin by classifying your product into its appropriate category or sector. Different types of products fall under specific regulations. For example, medical devices, machinery, electrical products, toys, and cosmetics each have their own set of regulations.
2. **Research Directives and Regulations:** Identify the relevant directives or regulations that pertain to your product category. For instance, machinery may fall under the Machinery Directive (2006/42/EC), medical devices under the Medical Devices Regulation (MDR), and so on.
3. **Check Harmonized Standards:** Harmonized standards are technical specifications that provide a presumption of conformity with EU regulations. Check if there are any harmonized standards applicable to your product category. Harmonized standards are listed on the European Commission's official website or in the directives that apply to your product.
4. **Use Online Resources:** There are various online resources provided by the EU, such as the "Your Europe" portal or the "New Approach" website, that offer guidance on product regulations and requirements.
5. **Consult Notified Bodies:** Each EU member state has a designated authority responsible for overseeing product compliance. These authorities can provide guidance on which regulations apply to your product. (List of notified bodies can be found in NANDO database: https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies)
6. **Seek Legal and Regulatory Experts:** If you're uncertain about the applicable regulations, consider seeking advice from legal or regulatory experts who specialize in EU product compliance.

2 List of regulations applicable to hydraulic power units

The following directives and regulations apply to most of the hydraulic power units and when:

Table 1

Name (abbr.)	Number	Applies to
Machinery Regulation[1]	2023/1230	all machinery (all hydraulic power units)
Machinery Directive	2006/42/EC	all machinery (all hydraulic power units)
Pressure Equipment Directive (PED)	2014/68/EU	hydraulic power units with built in pressure equipment
Ecodesign Regulation	2019/1781	hydraulic power units using electric motors or variable speed drives
Low Voltage Directive (LVD)	2014/35/EU	hydraulic power units operating with input/output voltage between 50 and 1000 VAC or 75 and 1500 VDC
Electromagnetic Compatibility (EMC) Directive	2014/30/EU	hydraulic power units using electrical or electronic devices which may generate electromagnetic disturbances
ATEX Directive	2014/34/EU	hydraulic power units used in potentially explosive atmospheres
Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation	EC 1907/2006	all materials (all hydraulic power units)
Restriction of Hazardous Substances (RoHS) Directive	2011/65/EU	hydraulic power units using electrical or electronic equipment (EEE)
Waste Electrical and Electronic Equipment (WEEE) Directive	2012/19/EU	hydraulic power units using electrical or electronic equipment (EEE)

The machinery directive is mutually exclusive with PED, LVD and EMC Directives in terms of putting CE mark on the partly completed machinery, however the directives have to be followed and risks from all directives have to be taken into account when performing risk assessment of machinery. The only directive that supersedes the Machinery Directive is ATEX Directive and also the only case where CE mark is issued to hydraulic power units.

3 Directives and regulations in detail

This chapter will briefly describe each directive and present the part that applies to the hydraulic power units.

[1] Updated version of the Machinery Directive. (see chapter 3.1)

3.1 Machinery Regulation (2023/1230)

Machinery Regulation was published on 29. 06. 2023 and will enter into force on 20.01.2027. Machinery Regulation extends and updates Machinery Directive which is therefore repealed. Because of lack of time to study the regulation in detail only the most important changes from the machinery directive are pointed out. These are:

- A machine's operating instructions only need to be available digitally.
- Substantial modification of the machine is defined. Makes user the manufacturer with all the obligations that entails.
- Different conformity assessment procedures for different categories of machinery.
- Some paragraphs were amended.
- The definition of 'machine or related product' was expanded and now includes cobots – machines without programming or application. [2, 3]

3.2 Machinery Directive (2006/42/EC)

The main European directive concerning machinery and certain parts of machinery is Machinery Directive (2006/42/EC). Intent of the directive is to ensure a common safety level in machinery placed on the market or put in service in all member states and to ensure freedom of movement within the EU by stating that "member states shall not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of machinery which complies with [the] Directive". [4]

The Machinery Directive also applies to some other countries which are members of the European Single Market and are not part of the EU or European Economic Area (EEA). These countries include Norway, Iceland, Switzerland, Lichtenstein, Turkey, Andorra and San Marino. (European Commission, 2019)

This means that any machinery, safety component, interchangeable equipment, or accessory placed on the market within the EU must comply with the requirements outlined in the directive. It applies to both manufacturers based within the EU and those outside the EU who intend to sell machinery within the EU market. Non-EU

countries might have their own regulations and standards for machinery safety, but the Machinery Directive specifically applies to the EU member states.

Machinery Directive distinguishes between complete machinery and partly complete machinery [4]:

- **Complete machines** are those that are designed and constructed to perform a specific function on their own. They can be used as standalone equipment without the need for additional parts or modifications. These machines must meet the essential health and safety requirements outlined in the Machinery Directive before they can be placed on the EU market.
  Manufacturers of complete machines are responsible for ensuring that their products comply with the directive. This includes conducting risk assessments, designing machines with safety in mind, providing appropriate documentation, and affixing the CE marking to indicate compliance. The CE marking signifies that the machine meets the necessary standards and can be legally sold within the EU.
- **Partly complete machines** are components or sub-assemblies that are not capable of performing a specific function by themselves. They need further assembly, modification, or addition of other components to become functional machines. These components might include engines, frames, control systems, or other parts that, when combined, create a functioning machine.
  Incomplete machines are also subject to the Machinery Directive, although their requirements are slightly different. Manufacturers of incomplete machines must provide information on the intended use of the components and any potential risks associated with their assembly. This information helps the end user, who will complete the assembly, to understand how to safely integrate the incomplete machine into a complete and functional unit.

As it can be seen hydraulic power units in almost all cases fall into category of partly complete machines, therefore a closer look to obligations of manufacturer of partly completed machinery [6] (differences to complete machinery are in italic):

1. Identify the relevant product Directives/Regulations.
2. Identify the applicable requirements of the Directives/Regulations.
3. Identify an appropriate route to conformity.

4. Identify the relevant Harmonised Standards to which product could be designed.
5. Identify any other relevant Standards to which the product could be designed (if necessary).
6. Design the product to the requirements of the Standards.
7. Ensure the design of the product meets the requirements of the appropriate Directive/Regulation.
8. Ensure the product is marked as per the requirements of the identified Directives/Regulations/Standards.
9. Assembly Instructions (*Operating and Maintenance Instructions*) meet the requirements of the identified Directives/Regulations/Standards.
10. Complete and Document a Product Risk Assessment (It is advised that the Harmonised Standard EN ISO 12100:2010 is used for guidance).
11. Take action against any issues identified in the Risk Assessment.
12. Assess the product against the requirements of the appropriate Standards.
13. Assess the product directly against the requirements of the appropriate Directives/Regulations.
14. Take an action against any non-conformities identified in the Standard/Directive/Regulations Assessments. (Actions taken should be documented where necessary)
15. Compile the Technical File which consists of:
    a. description of partly completed machinery and its intended function,
    b. risk assessment documentation (requirements, protective measures),
    c. drawings and Schemes,
    d. references of the applied harmonized standards,
        e. description of applied technical specifications,
        f. calculation reports and test results to verify conformity of the machine,
        g. assembly instructions (*Operating and Maintenance Instructions),*
        h. *Declarations of incorporation for included partly completed machinery*
16. Produce and Sign the 'Declaration of Incorporation' (*'EC declaration of conformity'*) and
17. *Display CE mark on the product.*

If the product is classed as Partly Completed Machine only the Declaration of Incorporation and Assembly Instructions are required to be supplied to demonstrate conformity to a third party. Also the CE Mark must NOT be attached to the Partly

Completed Machine (Exception: if the partly complete machinery falls under ATEX directive – it must be CE marked according to ATEX directive).

The most important harmonized standards for safety of machinery and hydraulic power units referred to from machinery directive are [7]:

- EN ISO 4413:2010 - Hydraulic fluid power – General rules and safety requirements for systems and their components (ISO 4413:2010)
- EN ISO 4414:2010 - Pneumatic fluid power – General rules and safety requirements for systems and their components (ISO 4413:2010)
- EN ISO 12100:2010 - Safety of machinery – General principles for design – Risk assessment and risk reduction
- EN ISO 16092-3:2018 - Machine tools safety - Presses - Part 3: Safety requirements for hydraulic presses (ISO 16092-3:2017)
- EN IEC 62061:2021 - Safety of machinery - Functional safety of safety-related control systems
- EN 693:2001+A2:2011 – Machine tools – Safety – Hydraulic presses
- EN 982:1996+A1:2008 - Safety of machinery – Safety requirements for fluid power systems and their components – Hydraulics
- EN 983:1996+A1:2008 - Safety of machinery – Safety requirements for fluid power systems and their components – Pneumatics
- EN 12622:2009+A1:2013 - Safety of machine tools – Hydraulic press brakes
- EN 14673:2006+A1:2010 - Safety of machinery - Safety requirements for hydraulically powered open die hot forging presses for the forging of steel and non-ferrous metals

3.3 Pressure Equipment Directive (PED) (2014/68/EU)

The Pressure Equipment Directive (PED) is a European Union directive that establishes rules and regulations for the design, manufacturing, testing, and conformity assessment of pressure equipment. The directive was introduced to ensure a high level of safety for pressure equipment, which includes items such as vessels, piping, boilers, pressure accessories, and assemblies. Pump housings, manifolds etc. are not considered pressure vessels according to PED in any case. [8] Pressure vessels used in hydraulics are hydraulic accumulators and piping. If they fall

under the PED can be determined from Annex II of the PED. For hydraulic power units the following tables are applicable (Considering mineral oil and nitrogen are in fluid group 2): Table 2 – gas side of the accumulator; Table 4 – fluid side of the accumulator; Table 7 – gas side piping and Table 9 – fluid side piping (Figure 1).

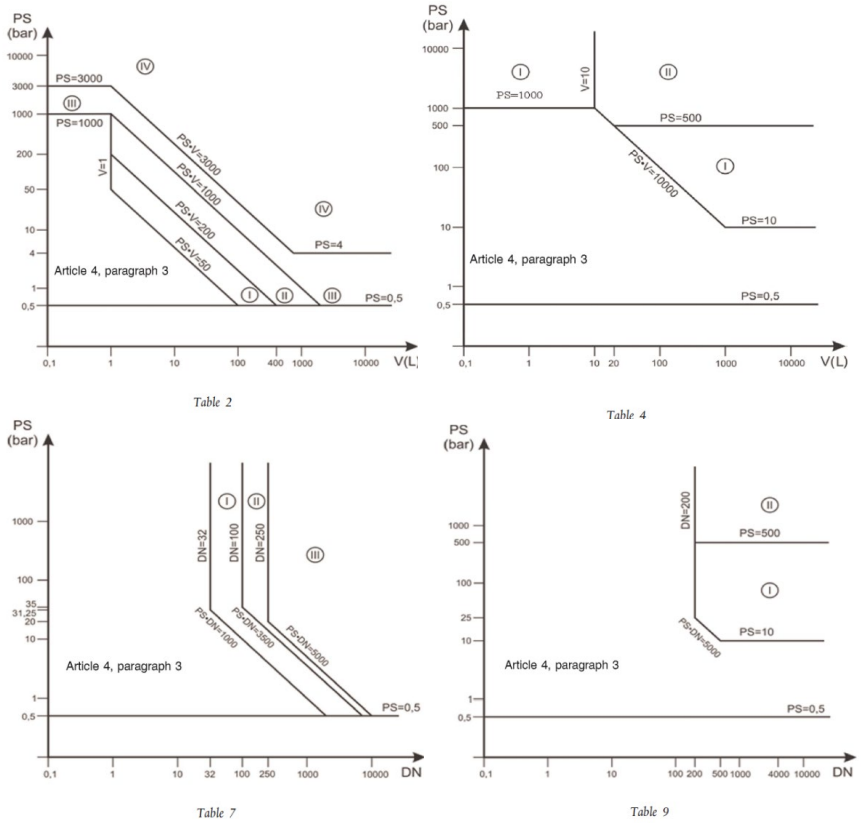

Figure 1: PED categories for pressure vessels and piping for fluid group 2 [8]

Accumulators must be checked on the gas side and on the oil side. The gas side is always stricter, therefore all accumulators greater than 1 l or P*V>50 bar l fall under PED. From Table 7 we can see that in rare cases piping on the gas side could fall under PED (DN>32 mm and p*DN>1000 bar mm) and therefore be PED certified (the PED certification procedure is not in scope of this article). Piping on the oil side almost never falls under ped as diameters greater than DN200 at pressures greater than 10 bar are rarely used in hydraulics. [8]

When an accumulator falls under PED, it must be purchased with valid PED certificate and adequately protected using a PED certified safety pressure relief valve.

How to properly protect the hydraulic accumulators is described in EN 14359 with circuit examples in Annex C [9]. Each accumulator must have a manual valve to be disconnected from the system, one ball valve to empty it back to tank and must be directly connected to PED certified safety pressure relief valve, which must not be used as a main system pressure relief valve at the same time as shown in Figure 2. When multiple accumulators are used in parallel there is no need to have a separate ball valve and safety pressure relief valve for each accumulator. A pressure gauge which cannot be disconnected from the accumulator by means of a ball or a check valve must be included so that the actual accumulator pressure may be read out before starting maintenance work on the machine.

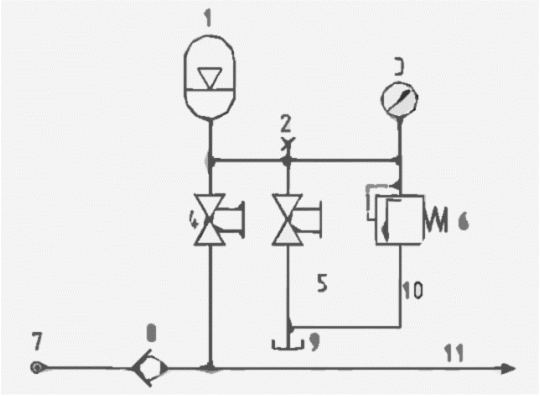

Figure 2: Basic accumulator protection circuit [9][9]

One important thing to note is that hydraulic power unit as partly completed machine does not fall directly under PED directive and thus must not be CE marked, because it only uses components with PED certificate.

3.4 Ecodesign Regulation (2019/1781)

Ecodesign Regulation limits the use of inefficient motors and variable frequency drives. Therefore it applies to all hydraulic power units using AC electric motors. Minimum energy efficiency required by the regulation for motors is depicted in Figure 3 and was applied according to the following timetable [10]:

- from 1 July 2021:
  - the energy efficiency of three-phase motors with a rated output equal to or above 0,75 kW and equal to or below 1000 kW, with 2, 4, 6 or 8 poles, which are not Ex eb increased safety motors, shall correspond to at least the IE3
  - the energy efficiency of three-phase motors with a rated output equal to or above 0,12 kW and below 0,75 kW, with 2, 4, 6 or 8 poles, which are not Ex eb increased safety motors, shall correspond to at least the IE2
  - the power losses of variable speed drives rated for operating with motors with a rated output power equal to or above 0,12 kW and equal to or below 1000 kW shall not exceed the maximum power losses corresponding to the IE2 efficiency level
- from 1 July 2023:
  - the energy efficiency of Ex eb increased safety motors with a rated output equal to or above 0,12 kW and equal to or below 1000 kW, with 2, 4, 6 or 8 poles, and single-phase motors with a rated output equal to or above 0,12 kW shall correspond to at least the IE2.
  - the energy efficiency of three-phase motors which are not brake motors, Ex eb increased safety motors, or other explosion-protected motors, with a rated output equal to or above 75 kW and equal to or below 200 kW, with 2, 4, or 6 poles, shall correspond to at least the IE4.

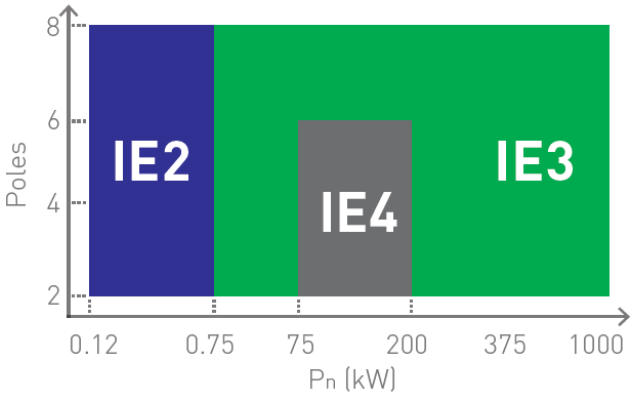

Figure 3: Current (after 1 July 2023) minimal motor efficiency classes for three phase motors [11]

3.5 Low Voltage Directive (LVD) (2014/35/EU) and Electromagnetic Compatibility (EMC) Directive (2014/30/EU)

Hydraulic power units do not directly fall under Low Voltage Directive [12] and Electromagnetic Compatibility Directive [13], therefore they cannot bear CE mark as required by LVD and EMC. If the components that fall under LVD (input/output voltage between 50 and 1000 VAC or 75 and 1500 VDC) or EMC (electronics emitting electromagnetic noise) are used they must have applicable certificates available, so that they may be used in the EU. Although when only the Machinery Directive applies the risks from other directives still has to be taken into account.

One special case that often causes confusion in practice is the CE marking of the electrical cabinets, which are often part of hydraulic power units. To clarify the topic we need to distinguish between who is the manufacturer of the electrical cabinet and the machine. [14]

- **Machine manufacturer is the cabinet builder for his own machine:** No CE marking on electrical cabinet required as the electrical cabinet is not placed separately on the market, therefore only machinery directive applies.
- **Cabinet builder builds the cabinet according to manufacturer's technical documents:**
  Cabinet builder is not deemed to be the manufacturer in this case, so no CE marking on electrical cabinet required as the electrical cabinet is not placed separately on the market, therefore only machinery directive applies.
- **Cabinet builder designs and builds the cabinet for the machine manufacturer:**
  Cabinet builder is responsible for compliance with EU regulations. There are multiple cases:
  a. **Cabinet does not contain safety functions,** therefore does not fall under machinery directive and therefore needs to follow LVD, EMC and other directives and thus has to be CE marked.
  b. **Cabinet contains safety functions:**
     i. **When safety functions are implemented entirely by the use of safety components,** the cabinet does not fall under machinery directive and therefore needs to follow LVD, EMC and other directives and thus has to be CE marked. All the information regarding the safety

components have to be transferred from the cabinet builder to machine manufacturer.

ii. **When safety functions are implemented by the use of normal components,** the cabinet falls under machinery directive and the cabinet builder has to follow the machinery directive for partly complete machinery.

3.6 ATEX Directive (2014/34/EU)

This directive applies to manufacturers, distributors, and importers of equipment and protective systems intended for use in potentially explosive atmospheres within the European Economic Area (EEA). It also includes components necessary for the safe operation of such equipment.

The directive classifies equipment into different categories based on the level of protection required. Categories are divided into equipment intended for use in Zones 0, 1, 2 (gas/vapor environments) or Zones 20, 21, 22 (dust environments) in terms of their potential explosive nature. The categories help determine the level of conformity assessment required.

Manufacturers are required to carry out additional risk assessment procedure applicable to explosive atmospheres. Primary hazards (potential ignition sources) in explosive atmospheres include (EN ISO 80079-36 Table B.1): hot surfaces, mechanically generated sparks, flames and hot gases, electrical sparks, electrical stray currents and cathodic corrosion protection, static electricity, lightning strike, electromagnetic waves, ionizing radiation, high-frequency radiation, ultrasonic waves, adiabatic compression, chemical reactions. All of those hazards have to be considered along with the applicable ATEX zone and materials present. Using ATEX certified components (motors, level indicators, sensors, paint, materials, etc.) simplifies the risk assessment process and reduces number of potential ignition sources.

When a hydraulic power unit conforms to ATEX Directive it has to be CE marked along with the appropriate ATEX classification. [15]

Important standards for ATEX are:

- EN 1127-1: "Explosion prevention and protection. Part 1: Basic concepts and methodology"
- EN ISO 80079-36: "Explosive atmospheres. Part 36: Non-electrical equipment for explosive atmospheres. Basic method and requirements"
- EN ISO 80079-37: "Explosive atmospheres. Part 37: Non-electrical equipment for explosive atmospheres. Non-metallic"
- IEC 60079-0: "Explosive atmospheres. Part 0: General requirements"

These standards provide guidelines and requirements for ensuring safety in explosive atmospheres, including methods for preventing and protecting against explosions and other related hazards.

3.7 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC 1907/2006)

REACH primarily focuses on the registration, evaluation, authorization, and restriction of chemical substances and their impact on human health and the environment. It doesn't directly regulate machines or their mechanical parts. [16] However, there are scenarios where REACH could indirectly affect machines and their parts:

1. **Substances in Machines:** If a machine or its parts contain chemical substances that are subject to REACH regulations, the manufacturers of those substances or articles may have obligations under REACH. For instance, if a machine's components contain substances of very high concern (SVHCs) in concentrations above 0.1 % by weight, there might be communication requirements down the supply chain about their presence.
2. **Materials Used:** If the manufacturing of machines involves the use of chemicals, whether for surface treatments, coatings, lubrication, or other purposes, the manufacturers of those chemicals must comply with REACH requirements.
3. **Importers and Manufacturers:** Companies importing or manufacturing machines within the EU may need to consider REACH if their machines contain substances in quantities above 1 ton per year. While the main focus

of REACH is on chemical substances, these substances can be used in various ways in the production of machines.

4. **Articles Containing SVHCs:** If machines or their parts contain substances of very high concern (SVHCs) above the 0.1 % threshold, downstream users might have communication obligations to inform their customers about the presence of these substances. This is especially relevant if the substances are intended to be released during normal use.
5. **REACH Compliance of Components:** Manufacturers of machines might request information about the chemical substances used in the components they purchase to ensure compliance with REACH regulations. This is to ensure that no restricted or unauthorized substances are present.
6. **End-of-Life Considerations:** REACH regulations can affect the disposal and recycling of machines containing certain chemical substances, especially substances that are restricted or require authorization. Proper management and communication about these substances become important during the end-of-life phase of machines.

It's important to understand that REACH is primarily concerned with chemical substances and their impact on human health and the environment. While REACH may not directly regulate machines and their parts as mechanical entities, the chemical components within those machines could fall under REACH's scope depending on their properties and usage. REACH obliges manufacturers to get the information about the SVHCs in parts used to build the machine, combine those information and pass it on to the machine builder or end user.

3.8 Restriction of Hazardous Substances (RoHS) Directive (2011/65/EU) and Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU)

Similarly as with LVD and EMC Directive, hydraulic power units do not fall directly into this directives, but some demanding customers may want information that all Electrical and Electronic Equipment (EEE) that is used on the hydraulic power unit are RoHS compliant. RoHS restricts the use of certain hazardous substances in quantities larger than 0,1 %[2](mass) in EEE in order to protect human health and the environment. These substances are: Lead (Pb), Mercury (Hg), Cadmium (Cd),

[2] Except for cadmium for which the limit is 0,01 %

Hexavalent Chromium (Cr6+), Polybrominated Biphenyls (PBB), Polybrominated Diphenyl Ethers (PBDE). [17]

The Waste Electrical and Electronic Equipment (WEEE) Directive is a European Union regulation that aims to minimize the environmental impact of electrical and electronic equipment waste. It establishes guidelines for the collection, recycling, and disposal of such waste to reduce its impact on the environment and human health. WEEE Directive requires users of EEE to increase recycling awareness by mentioning in the assembly instructions that the partly complete machinery also includes EEEs which must be disposed separately from unsorted municipal waste. [18]

7 Conclusion

In conclusion, European directives play a pivotal role in harmonizing regulations and standards across the European Union (EU) member states, facilitating the free movement of goods and promoting safety, health, environmental protection, and consumer rights. These directives cover a wide range of industries and topics, ensuring that products placed on the EU market adhere to common requirements, enhancing market efficiency, and fostering cross-border trade.

Each directive is tailored to address specific challenges within its respective domain, outlining essential requirements, conformity assessment procedures, and obligations for manufacturers, importers, and distributors. The Machinery Directive stands out as a cornerstone within the framework of European directives, playing a pivotal role in ensuring the safety of machinery and equipment placed on the market and used within the European Union (EU). With a focus on harmonization, risk reduction, and enhanced consumer protection, the Machinery Directive embodies the principles of standardization and cooperation among member states.

The Machinery Directive addresses a broad spectrum of machinery, ranging from industrial equipment to consumer products, imposing stringent requirements that encompass design, manufacturing, and operation. By establishing essential health and safety requirements, the directive sets the groundwork for risk assessment and mitigation, promoting the development of safer, more reliable machinery.

Manufacturers bear a significant responsibility in complying with the Machinery Directive, conducting thorough risk assessments, adhering to essential requirements, and employing recognized safety standards. The CE marking, affixed upon successful conformity, is a testament to a product's compliance with the directive's stipulations, thereby fostering consumer confidence and facilitating trade across EU borders.

Conformity assessment procedures outlined in the directive facilitate consistent evaluation processes while acknowledging the varying degrees of risk posed by different machinery. Involvement of notified bodies, when necessary, ensures an additional layer of oversight and expertise.

However, the directives are not a static entities. They adapt to technological advancements and emerging risks, ensuring that its regulations remain current and relevant. Stakeholders must remain vigilant, staying informed about updates and revisions, and actively participating in the dialogue surrounding machinery safety. The directives underscore the EU's commitment to safeguarding the welfare of its citizens, promoting workplace safety, and fostering a competitive market environment. It bridges the gap between innovation and responsibility, emphasizing that progress can coexist with precaution.

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