

CE Essential Health & Safety Regulations (EHSR's)

Directive 2006/42/EC

Machine manufacturers, and manufacturers of other types of products that may be found in a manufacturing environment, are frequently asked by their customers to confirm their product meets the "EHSR's". Often times, the person asking for the EHSR's doesn't know what they are asking for or even what it means = they just know that it is important that the product comply with the "EHSR's.

What are the EHSR's? "EHSR" is an abbreviation for "Essential Health & Safety Regulations". The EHSR's are a list of the potential hazards that must be considered in the design of a "machine" according to the CE Machinery Directive. The EHSR's are contained in Annex I of the Machinery Directive.

<u>The Potential Hazards:</u> Within the Essential Health & Safety Requirements of the CE Machinery Directive, there is a long list of possible hazards, safety features, and user/machine interaction to be considered for each machine that must comply with the CE Machinery Directive. This list includes many "essential requirements" including:

- Adequate Machine Lighting
- Movement/Handling of the Machine
- Emergency Stop Actions
- Stability
- Guarding
- Noise & Acoustics
- Vibration
- Markings & Instructions

- Ergonomics
- Reliability of Controls
- Power Failure
- Moving Parts
- Electrical Safety
- Maintenance
- Radiation
- Assembly/Installation

<u>Product Specific Considerations:</u> In addition to the list of general hazards and requirements, the EHSR's also contain requirements applicable to several specific types of machines and machine components including:

- a) Foodstuffs Machinery
- b) Cosmetics Machinery
- c) Pharmaceutical Machinery
- d) Hand-held & Hand-guided Machinery
- e) Work Positions & Location of Controls
- f) Batteries
- g) Pulleys, Drums, & Wheels
- h) Seating
- i) Hazards from Lifting Operations
- j) Hazards from Underground Work
- k) Hazards from Lifting of Persons



EHSR Compliance Report: A CE marked machine that complies with the Machinery Directive should have a report kept in its Technical Construction File that documents how the product complies with the EHSR's. The process of reviewing the EHSR's and preparing the compliance report includes a review of the machine's Risk Assessment (RA). The RA should list all potential hazards with the machine and the associated mitigations. This includes all potential hazards listed in the EHSR's. The EHSR compliance report should identify all hazards within the product and therefore correlate with the RA. The EHSR compliance report should also identify the methods of protection for each of the hazards and the related safety standards used to evaluate the protection methods for compliance.

Of course not all hazards exist in all products. The EHSR report should also clearly indicate which hazards on the EHSR list are not applicable to the machine and why. When complete, the RA and the EHSR report should work together with many references to the RA in the EHSR report.

<u>EHSR's are Proprietary:</u> Your EHSR report is confidential and should be kept in the product's Technical Construction File (TCF) – which is also confidential. You are not required to provide your EHSR report to anyone other than in response to a formal request from a European Union official to see the product TCF.

EHSR's & Other Directives: While other CE Directives contain safety requirements, only the CE Machinery Directive uses the term "Essential Health & Safety Requirements". The Low Voltage Directive title for safety requirements is "Safety Objectives". Therefore, if a customer or other person asks about your "EHSR's", whether they know it or not this can only apply to products that fall under the CE Machinery Directive. Therefore, in response to customer requests for the machine's EHSR report:

- a) For Machines that meet the Machinery Directive, provide a copy of the CE Declaration of Conformity which should list the Machinery Directive and the standards used to verify compliance. You may also wish to indicate that the ESHR's are a subset of the Machinery Directive to which the product complies however, the EHSR report contains proprietary information and in accordance with CE Machinery Directives guidelines, it is maintained in the Technical Construction File that is only available to EU officials.
- b) For Products that meet the Low Voltage Directive (not a "machine"), provide a copy of the CE Declaration of Conformity which should list the Low Voltage Directive and the standards used to verify compliance. You may also wish to indicate that the ESHR's are a subset of the Machinery Directive which is not applicable to the product.

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