

Basic principles



Requirements for placing machinery on the market in the European Economic Area (EEA)

Contents

1 Basic principles	2		
1.1 EC Treaty eliminating trade barriers	3		
1.2 European Directives and Standards	3		
1.2.1 EC Directives	3		
1.2.2 EC Machinery Directive	4		
1.2.3 European Standards	4		
1.3 Placing machinery on the market	5		
1.4 Risk assessment	5		
1.5 Essential health and safety requirements	7		
2 Technology and processes	8		
2.1 Technical documentation	9		
2.1.1 General requirements	9		
2.1.2 Technical documentation for machinery	9		
2.1.3 Technical documentation for partly completed machinery	9		
2.2 Instruction handbook, assembly instructions	10		
2.2.1 General principles for the drafting of instructions	10		
2.2.2 Instruction handbook	11		
2.2.3 Assembly instructions for partly completed machinery	14		
2.3 Conformity assessment procedure	14		
2.3.1 Machinery not referred to in Annex IV	14		
2.3.2 Machinery referred to in Annex IV	14		
2.3.3 Partly completed machinery	15		
2.4 Declarations	15		
2.4.1 ED Declaration of Conformity	15		
2.4.2 Declaration of Incorporation	16		
2.5 CE Marking	16		
2.6 Interlinked machinery (assembly of machinery)	17		
2.6.1 Special requirements for interlinked machinery	17		
2.6.2 Applying the Machinery Directive to interlinked machinery	17		
2.6.3 Definition of “assembly of machinery”	18		
		2.6.4 Applying the Machinery Directive to an assembly of machinery	18
		2.6.5 Decision steps	19
		2.6.6 Examples of application	20
		2.7 Market surveillance and product liability	21
		2.7.1 Market surveillance	21
		2.7.2 Safeguard clause	21
		2.7.3 Product liability	22
		2.8 Test and Certification Body Printing and Paper Converting	23
		2.8.1 Test and Certification system provided by the German Social Accident Insurance (DGUV Test)	23
		2.8.2 GS sign, DGUV Test sign	23
		2.8.3 Euro-Test sign (ET sign)	23
		2.9 Placing new units to be incorporated in existing machines on the market	24
		2.10 Second-hand machines	24
		2.10.1 Import of second-hand machines into the European Economic Area (EEA)	24
		2.10.2 Placing on the market of second-hand machinery from EEA countries	24
		2.11 Direct import of machinery by users	27
		3 Annex	28
		Annex 1 Definitions	29
		Annex 2 Requirements for placing machinery and safety components on the market	31
		Annex 3 Sample 1 EC Declaration of Conformity	32
		Annex 4 Sample 2 EC Declaration of Incorporation	34
		Annex 5 Sources of supply	35

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Introduction

Starting January 1st, 1995, all machinery supplied in EC countries must be designed and constructed to comply with the Machinery Directive. Manufacturers need to acknowledge and satisfy the requirements laid down in the Machinery Directive before placing a machine on the market. Meanwhile, the Machinery Directive has been revised.

The present version of the EU Machinery Directive [2006/42/EG](#) is more specific in some respects.

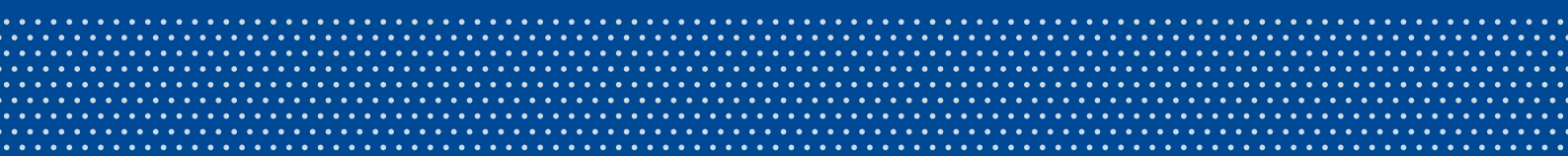
On June 29, 2023, the new EU Machinery Regulation 2023/1230 was published in the Official Journal of the European Union and will come into force after a transitional period of 42 months from January 20, 2027. Until then, the EC Machinery Directive 2006/42/EC will remain in force.

This publication is intended to resolve uncertainties and give guidance. Special consideration was given to those printing and paper converting machines which are not included in the list provided in Annex IV of the Machinery Directive.



1

Basic principles

- 1.1 EC Treaty eliminating trade barriers
 - 1.2 European Directives and Standards
 - 1.3 Placing machinery on the market
 - 1.4 Risk assessment
 - 1.5 Essential health and safety requirements
- 

1 Basic principles

1.1 EC Treaty eliminating trade barriers

On January 1st, 1993, the Single European Market came into force. The Single European Act supplementing the Treaty of Rome led to an economic union, the cornerstone of the EC domestic market. Health and safety regulations – in particular when being applied during the design and construction phase of machinery – may constitute a significant economic impact; hence it was a logical consequence to make them form part of the Supplementary Treaties. The problem of eliminating

technical trade barriers was solved by applying a New Approach, i. e. by devising framework directives in accordance with Article 95 of the EEC Treaty (creating the European domestic market), which would then be supplemented by standards stipulating the more specific requirements. The EFTA (European Free Trade Association) states have agreed to adopt this system which led to widening the EC domestic market into the so-called European Economic Area (EEA).

The EEA consists of

■ **EFTA member states:**

Iceland, Liechtenstein and Norway

■ **EC member states:**

Belgium, Bulgaria, Croatia, Denmark, Germany, Estonia, Finland, France, Greece, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Sweden, Slovakia, Slovenia, Spain, the Czech Republic, Hungary and Cyprus



1.2 European Directives and Standards

1.2.1 EC Directives

Basically, all European principles of relevance to occupational health and safety are laid down in the form of directives. EC Directives in accordance with Article 95 of the EC Treaty stipulate the requirements for technical products. Member states are not allowed to reduce the level of integrity or to require a higher level. In effect, member states have to implement EC Directives into national law without any alterations.

EC Directives are based on the following principles:

- Directives only stipulate the essential health and safety requirements.
- The European standardising bodies (CEN, CENELEC) are mandated with the task of setting up technical stipulations that conform to the essential safety requirements specified in the directives.
- These technical specifications are called “harmonised standards”. Their application is voluntary.

Requirements for placing machinery on the market in the European Economic Area (EEA)

- National bodies are bound to presume that the machinery designed and constructed in accordance with such harmonised standards is in compliance with the essential health and safety requirements laid down in the directives (“presumption of conformity”).

1.2.2 Machinery Directive 2006/42/EC

Among the directives established under Article 95 of the EC Treaty, the EC Machinery Directive 2006/42/EC of the European Parliament and of the Council plays a key role.

The Directive does not describe measures for specific groups of machinery, but it specifies the overall and essential health and safety requirements common to all machines and equipment within the scope of the Directive.

This also includes power-operated printing and paper converting machines. In Germany, the Machinery Directive was transposed into national law by the 9th Ordinance (Machinery Ordinance) to the Product Safety Act.

Machinery in the sense of the Machinery Directive is

- 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, irrespective of whether the assembly is able to function on its own or only when joined together.
- 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.

The Directive also covers partly completed machinery, interchangeable equipment, safety components which are independently placed on the market such as components for two-hand controls, lifting accessories, chains, ropes and webbing (designed and constructed as part of lifting machinery or lifting accessories) and removable drive shafts.

“Partly completed machinery” means an assembly or equipment which is incorporated or assembled with other machinery or equipment to form machinery in the sense of this Directive. “Partly completed machinery” has also sometimes been termed partial machinery or machinery not ready for use.

Excluded from the scope of the Machinery Directive are a number of parts and devices which are explicitly mentioned. This includes electric and electronic products such as motors, video units, office machines etc. The essential health and safety requirements for machinery are laid down in Annex I of the Machinery Directive, setting out the actual principles for the design and construction of machines (for availability see under “Brochures available”). Annex I, therefore is in fact the basis for manufacturers to work on.

1.2.3 European Standards

The high level of integrity in the field of health and safety is ensured by European standards which – on the basis of the requirements laid down in the Machinery Directive – deal with the more specific issues of the respective machinery. For technical harmonisation and standardisation, a new approach was established which is based on the following principles:

- Directives specify essential safety requirements.
- Harmonised standards stipulate technical requirements. Machinery constructed in accordance with these standards must be presumed to comply with the relevant essential safety requirements.

For standards to be harmonised they must be drafted under a mandate of the European Community and be published in the Official Journal of The European Community.

The provisions made in these standards deal with specific technical requirements. Applying these standards to the design and construction of machines will lead to conformity with the essential safety requirements of the Machinery Directive.

The manufacturer proves compliance with the Machinery Directive by declaring that his machinery is built in accordance with the respective standards. It is thus presumed that machinery complying with the specific harmonised standards will also be in conformity with the essential requirements of the Machinery Directive.

If machines are not built in accordance with harmonised standards but instead in accordance with the essential requirements of the Machinery Directive, there is a wide range of interpretation with regard to the technical requirements.

European standards are divided into three main categories:

- **Type A standards** setting out the principles and essential requirements for machine safety applicable to all types of machinery (for example EN ISO 12100-1 and -2).
- **Type B standards** defining safety aspects that apply to a wide range of machinery (B1 standards) or containing stipulations for safety-related components which are being used throughout a number of different types of machinery (B2 standards).
- **Type C standards** defining the safety requirements specific to a particular machine or group of machines (for example EN 1010-1: Safety of Machinery – Safety Requirements for the Design and Construction of Printing and Paper Converting Machines; Part 1: Common Requirements). C-type standards refer back to standards type A, B1 or B2 as far as feasible.

1.3 Placing machinery on the market

Following the stipulations of the Machinery Directive, the manufacturer or his authorised representative shall, before placing machinery on the market, satisfy the following requirements:

- A risk assessment (see clause 1.4) must be carried out.
- Machinery must comply with the requirements laid down in Annex I of the Machinery Directive (see clause 1.5).
- The technical documentation of the machinery must be supplied (see clause 2.1).
- The operating instructions (or assembly instructions for partly completed machines) must be produced and accompany the machine (see clause 2.2).
- The Conformity Assessment Procedure must have been carried out (see clause 2.3).

- The Declaration of Conformity or Incorporation must be produced and accompany the machine (see clause 2.4).
- The CE marking must be affixed to the machine and be distinct, legible and permanent. It consists of the two letters CE (see clause 2.5). There is no CE marking for partly incompleated machinery.

These requirements equally apply to manufacturers supplying items of machinery or assemblies subcontracted from different origin and to users assembling machinery for their proper application.

Machinery which does not fulfil the requirements set out above is not allowed to be placed on the market.

1.4 Risk assessment

In addition to building the machine, the manufacturer must also carry out a risk assessment to determine what hazards the machine poses or what hazards may arise and how these can be reduced or prevented (see EN ISO 12100). The manufacturer may design and construct the machine in line with published European standards.

In the absence of a respective standard, it is recommended to design and construct the machine on the basis of a standard describing similar risks. Risk assessment will then list the standards applied and contain an analysis of the protective measures implemented.

The aim is to make the machine as safe as possible for the user and this aim must be achieved under the conditions existing at the time of construction.

The conditions applicable are

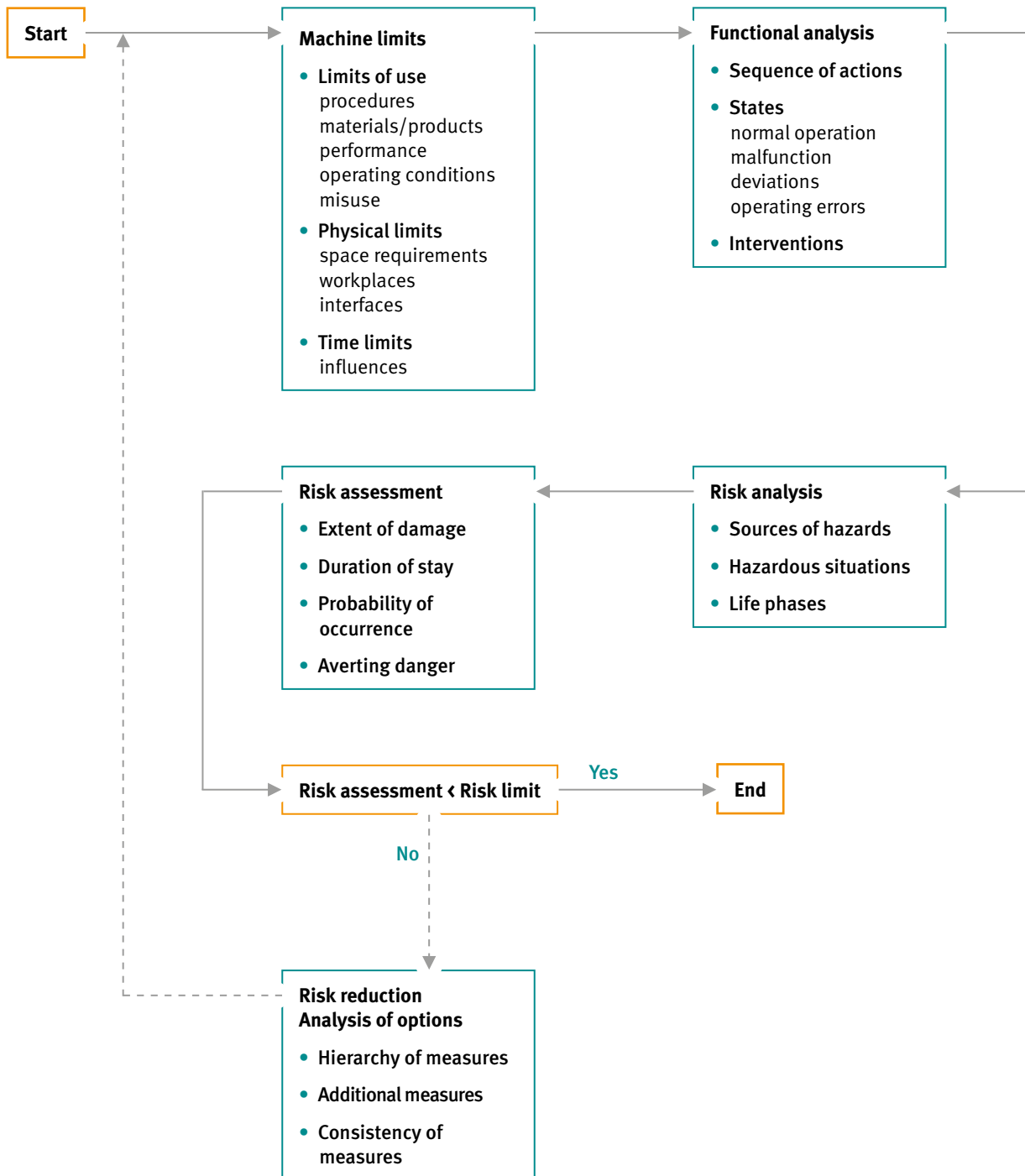
- The state of the art (standards, technical regulations),
- technical requirements,
- economic requirements.

Requirements for placing machinery on the market in the European Economic Area (EEA)

The iterative process of analysing and of elimination and reduction of risks must take account of the

intended use and any reasonably foreseeable misuse of the machine.

The results of risk assessment will then serve as basis for design and construction of the machine. The risk assessment must be documented and be supplied as part of the Technical documentation (see clause 2.1).



Risk assessment procedure

1.5 Essential health and safety requirements

The essential health and safety requirements for the design and construction of machinery are listed in Annex I of the Machinery Directive.

The principle is that the manufacturer or his authorised representative carries out a risk assessment to identify the health and safety requirements applicable to his machine.

Design and construction of the machine must be such that the machinery will function as intended and that it can be operated, adjusted and maintained without putting persons at risk.

When deciding on possible solutions, the manufacturer has to apply the following principles:

1. Eliminate or reduce risks as far as possible (inherently safe design and construction of machinery);
2. Provide safety measures for hazards which cannot be eliminated (safeguarding danger points by safety devices);
3. Warn the user of any residual risks prevailing due to shortcomings of the safety measures adopted; inform the user where job training or special skills of the operating personnel are required and indicate where personal protection equipment is needed (danger warning).

The safety measures provided must ensure that risks are eliminated throughout the entire anticipated life of the machine, including the time of transportation, mounting, commissioning, decommissioning and disposal.

When designing and constructing machinery and when drafting the instruction handbook, the manufacturer or his authorised representative are under the obligation to envisage not only the intended use of the machine, but also any misuse which can be reasonably foreseen.

Machinery must be designed and constructed in such a way that its abnormal use is prevented. The instruction handbook must identify any misuse of the machine, which is known to occur from experience.

Machinery must be supplied with all the special equipment and accessories requisite for its safe adjustment, maintenance and operation.

Special issue “noise”

The Machinery Directive requires all machines to be constructed “taking account of the technical progress and the availability of means reducing noise”.

How can machine manufacturers find out about the latest technical advances? Annex E to EN 1010-1:2004+A1 lists the target noise levels (noise emission levels) of several machines which represent the latest technical advances. Noise emission levels for other machines can be found in the current draft standard prEN ISO 12643-1, Annex D.

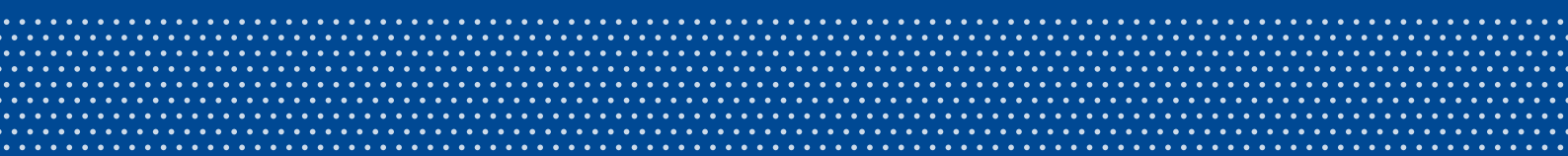
The German-based testing and certification body for printing and paper converting publishes an information sheet (no. 923) on noise, which explains the differences between emission and immission levels.

In Germany, we applied the target noise levels specified in Annex 1 of the Noise and Vibrations Occupational Safety and Health Ordinance, Part 3, (TRLV Lärm Teil 3).



2

Technology and processes

- 2.1 Technical documentation
 - 2.2 Instruction handbook, assembly instructions
 - 2.3 Conformity assessment procedure
 - 2.4 Declarations
 - 2.5 CE Marking
 - 2.6 Interlinked machinery
(assembly of machinery)
 - 2.7 Market surveillance and product liability
 - 2.8 Test and Certification Body Printing
and Paper Converting
 - 2.9 Placing new units to be incorporated in
existing machines on the market
 - 2.10 Second-hand machines
 - 2.11 Direct import of machinery by users
- 

2 Technology and processes

2.1 Technical documentation

2.1.1 General requirements

The technical documentation must allow verifying that the machinery complies with the requirements of the Machinery Directive. It has to describe the design, construction and operation of the machinery to the extent required for verification. The documentation must be compiled in one or more official languages of the Community.

On request, the documents must be compiled by the person specified on the EC Declaration of Conformity and provided to the authorities within a reasonable period of time.

The documentation must be stored for at least 10 years after the date of manufacture of the last machine for availability to the competent national authorities.

For machines produced outside the EEA, an authorised representative must be designated who is established in the EEA and is capable of providing the documentation. The complexity and type of the technical documentation depend on what is technically required to verify conformity of the machinery with the standards or with the essential health and safety requirements.

2.1.2 Technical documentation for machinery

Before signing the Declaration of Conformity and affixing the CE sign on the machine, the following technical file has to be compiled and produced in one or more of the official languages of the Community:

- a general description of the machinery,
- an overall drawing of the machine including drawings of the control circuits (especially safety-related control circuits) as well as descriptions and explanations required for understanding the operation of the machine,
- full detailed drawings including, where appropriate, calculations, test results and certificates where requisite for proof of compliance with the essential safety requirements,
- documentation of the risk assessment demonstrating which procedure was followed, including:
 - a list of essential health and safety requirements which apply to the machinery,
 - a description of the safety measures applied to eliminate hazards or reduce the risks identified and, where appropriate, an indication of the residual risks existing on the machinery,
- the standards and other technical specifications applied, indicating the essential health and safety requirement covered by these standards, all technical reports including the results of tests carried out by the manufacturer or by a notified body assigned by the manufacturer or his authorised representative,
- a copy of the instruction handbook (see clause 2.2.2),
- where appropriate, the Declaration of Incorporation and the assembly instructions for partly completed machinery (see clause 2.2.3),
- where appropriate, copies of the EC Declaration of Conformity for machines or products incorporated in the machinery,
- a copy of the EC Declaration of Conformity,
- for machinery manufactured in series, a list of the internal measures implemented to ensure compliance with the provisions of the Machinery Directive (for example quality assurance system, checks carried out on the basis of check lists and tests).

2.1.3 Technical documentation for partly completed machinery

Before signing the Declaration of Incorporation, the following technical file has to be compiled and produced in one or more of the official languages of the Community:

- a general description of the machinery,
- an overall drawing of the partly completed machinery and drawings of the control circuits,
- full detailed drawings including, where applicable, calculations, test results and certificates where requisite for proof of compliance of the partly completed machinery with the essential safety requirements,

Requirements for placing machinery on the market in the European Economic Area (EEA)

- documentation on the risk assessment demonstrating which procedure was followed, including:
 - a list of the essential health and safety requirements which were applied and observed,
 - a description of the safety measures applied to eliminate or reduce identified hazards and, where appropriate, an indication of the residual risks existing on the machinery,
- the standards and other technical specifications applied, indicating the essential health and safety requirements covered by these standards, all technical reports including the results of tests carried out by the manufacturer or by a notified body assigned by the manufacturer or his authorised representative,
- assembly instructions required for incorporation into machinery (see clause 2.2.3),
- for machinery manufactured in series, a list of the internal measures implemented to ensure compliance of all partly completed machines with the respective essential health and safety requirements of the Machinery Directive.
- Copy of the EC Declaration of Incorporation



2.2 Instruction handbook, assembly instructions

2.2.1 General principles for the drafting of instructions

Instructions are an integral part of product supply. The information contained must allow the machine to be used correctly and should envisage all foreseeable user obligations.

Instructions also constitute an integral part of the concept of safe design of machines. As such they must address all information required to avoid intolerable user risks and malfunctions or shortcomings of Operation (for the drafting of instructions see EN 62079).

Instructions are however not meant to compensate deficiencies in machine design. They are rather intended as a means of immediate assistance to prevent foreseeable misuse which could create a hazard.

Instructions must be unambiguous and easy to understand. They should not contain technical terms or be written in poor language. Unusual terms should be clearly defined.

For the benefit of the user, the principle underlying user information should be to initiate operator action in the sequence of “see – think – do”. How and Why questions should be raised and answered beforehand.

Close cooperation between engineers and designers is required to devise complete and consistent descriptions of all operational steps and warnings of hazards.

Where the foreseeable use of the machine will also be in non-industrial areas, special care should be taken to draft instructions in such a way that they can also be understood by non-professional personnel.

Textual passages and illustrations should be combined to reflect the latest findings in modern didactical developments. The course of actions must be presented in logical sequence.

The essential health and safety aspects should be covered in a separate chapter and it makes sense to put them at the beginning of the instructions. It may also appear useful to issue separate publications for certain incidents, for example a scheme to follow in case of malfunctions.

The material for the handbook (paper, board, plastic) should be selected with a view to resistance against contamination (oil, grease, dirty hands).

It is of considerable importance to devise instructions in such a way as to enhance user readiness to read them. Illustrations could be one possibility of making reading more attractive.

A well-devised instruction handbook helps to use and handle machines properly and with care.

2.2.2 Instruction handbook

All machinery must be accompanied by an instruction handbook in the official community language or languages of the member state where the machine is placed on the market and/or put into service.

The instruction handbook accompanying the machinery must either be the “original instruction handbook” or a “translation of the original instruction handbook” in which case the translation must be accompanied by the original instructions. Language versions must be marked as “original instruction handbook” or “translation of the original instruction handbook”.

As an exception, it is possible to supply the maintenance instructions drafted for use by the specialised staff mandated by the manufacturer or his authorised representative in one of the official community languages which the staff understands.

Instructions must address all technical safety requirements relevant under the conditions of the intended use.

Instructions shall not only relate to the intended use, but shall also take account of any reasonably foreseeable misuse.

Contents and layout of instruction handbooks intended for consumer use must take account of the general state of knowledge and the acumen that can reasonably be expected from such operators.

Significant changes of Machinery Directive

- The contents of the Declaration of Conformity must be incorporated in the instruction handbook. The Declaration of Conformity must also give the name and address of the person authorised to compile the technical file (person must be established in the EC). For samples of the Declaration of Conformity see Annex 3.
- For machinery and lifting equipment, the results of static and dynamic testing must be indicated (test report in accordance with Annex I 4.1.2.3 of the Machinery Directive 2006/42/EC).
- In addition to the sound pressure levels for all workstations, the maximum sound power level must always be declared if the sound pressure level at an individual workstation exceeds 80 db(A). In the case of very large machines, the A-weighted sound power level may be replaced by the A-weighted emission sound pressure levels measured at specified positions around the machine.

Emission values are often incorrectly used in practice. They are not immission values and should not be mixed up with the parameters relating to personal exposure (rating levels etc.).

Emission values serve to:

- provide a basis for comparison of similar machines constructed by different manufacturers
- allow objective assessment of machinery under the conditions specified in standards
- serve as a contractual basis when purchasing new machinery

The instruction handbook will basically cover the following aspects:

A. Information relating to machinery

- The business name and address of the manufacturer and his authorised representative;
- the designation of the machinery as marked on the machinery itself, with the exception of the serial number;
- the EC Declaration of Conformity or a document setting out the contents of the EC Declaration of Conformity and indicating particulars of the machinery (serial number and signature not required);
- description of the technical safety system of the machinery (overall drawings and cross sections of the machinery showing the safety related functions and protective devices such as interlocking guards, fixed guards, trip bars. All safety related devices must be described with regard to their function and effects,

Requirements for placing machinery on the market in the European Economic Area (EEA)

for example hold-to-run operation permitted while interlocking guards are open);

- description of the workstation(s) likely to be occupied by operators (including make-ready, maintenance and inspection, for example for cleaning or for web threading on rotary printing presses);
- description of the intended use of the machinery (area for which the machinery is intended, specification of material to be used; thickness, size, inks, cleaning agents and the like, where appropriate also indication of prohibited use of the machinery, for example use of explosive solvents, flash point of the solvents used, prohibition of specific dangerous substances);

Example:

“This machine is suitable for printing on paper with a maximum grammage of ... g/m² and a format size of ... It is not suited for printing inks with a flash point below ... °C”.

- the essential characteristics of tools which may be fitted to the machine;
- specification of spare parts to be used where the health and safety of operators can be affected;
- information on airborne noise of the machinery:
 - the A-weighted emission sound pressure level on workstations where it exceeds 70 db(A). Where this level is less or equal to 70 db(A), this fact must be indicated,
 - the peak instantaneous C-weighted emission sound pressure level at workstations, where it exceeds 63 Pa (130 dB in relation to 20 µPa),
 - the A-weighted maximum sound power level of the machinery where the A-weighted emission sound pressure level at workstations exceeds 80 db(A).

The values indicated must be those actually measured on the respective machinery or be determined on the basis of measurements taken for a technically comparable machine which is representative for the application intended.

In the case of very large machines, the A-weighted sound power level may be substituted by the A-weighted emission sound pressure levels measured at specified positions around the machine.

For noise measurements on printing and paper converting machines as well as paper making and finishing machines, EN 13023 “Safety of machinery – Noise measurement methods for printing, paper converting, paper making and finishing machines” applies.

Where harmonised standards are not applied, the most appropriate measuring method for the respective must be used to determine the machine sound levels. Where sound emission values are indicated, the uncertainties relating to these values must be specified. The machine operating conditions during measurement and the measuring method applied must be documented.

Where the workstation(s) are undefined or cannot be defined, measurements of the A-weighted sound pressure levels must be taken at a distance of 1 m from the surface of the machinery and at a height of 1,60 m from the floor or access level. The maximum emission sound pressure level and the measuring point where it is taken must be indicated.

- where applicable, information on radiation, gases, vapour, dust etc. emitted from the machine;
- information on electric supply (voltage, frequency, nominal operating current);
- where machinery is likely to emit non-ionising radiation which may cause harm to persons, especially persons with active or inactive implantable medical devices, information about the radiation to which operators and other persons may be exposed is required;
- information on equipment where required by C standards (for example specification of the overall response time, object detection capability and minimum distance of photoelectric beams on guillotines);
- requirements for machine stability throughout the life of the machinery.

B. Information relating to transport and handling of the machinery

- Where required, instructions for mounting the machine (points for attaching lifting equipment or for taking up loads by fork trucks), machine dimensions and weight (for example for selecting the right type of lifting equipment), where required, the position of the centre of gravity;
- Conditions under which machinery meets the requirements of stability during use, transportation, assembly, dismantling, when out of service, during testing and foreseeable breakdown.

C. Information relating to commissioning of machinery

- Installation and assembly instructions for reducing noise and vibrations (for example description of the substructure, provision of vibration-isolating elements);
- instructions for assembly, mounting and connection of the machinery, including drawings and circuit diagrams and attachments as well as the designation
- of the chassis or installation on which the machinery is to be mounted;
- where required, information about floor conditions (for example conductive flooring on certain areas around the machine for explosion protection);
- instructions for putting into service and operation of the machine and, if necessary, instructions for training of operators;
- space requirements for operation, maintenance and inspection (for example accessibility of switch cabinets);
- restrictions of environmental conditions (as far as required for the use of the machine: indication of temperature ranges, admissible moisture levels, electromagnetic radiation etc. which the machine is permitted to be exposed to);
- description of power supply connections, taking account of the direction of rotation of drives in case of three-phase current and, where required, particulars about the qualification of electricians (for example electrical engineers);
- where machinery is operated in explosive atmospheres, a summary of all requirements relating to environmental conditions (zoning for explosion protection, exhaust measures, measures for avoiding static loads, conductivity of flooring etc.);
- description of measures to be taken by the user before putting the machine into service where machinery is not assembled in a ready-to-use state by the manufacturer.

D. Information relating to the use of machinery

- Description of the function of controls (actuators, switches);
- instructions for safe adjustments and maintenance, including the necessary protective measures (instructions for adjustments and make-ready, handling of safety devices, adjustment of guards, knife changing on cutting devices);
- description of operating modes and means of stopping (for example hold-to-run control with related residual risks, special operating modes with related residual risks);
- identification of emergency stop areas on interlinked machinery, pointing out the need to instruct the operating personnel at regular intervals;

- information about residual risks that could not be avoided by machine design and remain in spite of safety precautions and complementary protective measures implemented (for example handling of dangerous substances when cleaning and replenishing, disposal, hazardous emission of substances, residual risks that cannot be avoided by technical measures in the delivery of sheet-fed printing presses, warning of hot surfaces behind guards that can be opened, warning of high voltage);
- warning of hazards generated by inadmissible use which is likely to occur (for example the need for pressure relief before replenishing liquids in vessels);
- instructions for fault finding and repair;
- instructions about protective measures to be taken by the user (in particular user-specific safety measures such as for example instructions for adjustment of guards, observance of safety distances between movable parts of the machine and surrounding structures etc.), where appropriate, the personal protection equipment to be provided (for example when handling hazardous substances);
- description of adjustments and maintenance to be carried out by the user as well as related preventive maintenance;
- instructions for the safe transport, handling and storage, indicating the weight of the machinery and of its various parts if these have to be transported regularly;
- instructions for removal and disposal of waste (for example waste paper with wet UV inks, PUR remains);
- description of measures to be taken by the user, including personal protection equipment to be provided.

E. Information relating to maintenance

- Type and frequency of inspections, in particular with regard to safety-related functions (brakes, clutches, safety devices, especially trip bars, pressure-sensitive mats, photoelectric beams etc.);
- instructions for maintenance carried out by the user or, where applicable, by skilled personnel (in particular instructions for replacing safety-related components such as filter screens for UV exposing equipment, conductive V-belts and gear belts in explosive areas, conductive hoses for combustible liquids; use of protective appliances such as knife covers for knife changing);
- as far as required for machine maintenance and inspection, the addresses of suppliers/importers and of service shops.

F. Safety-related information for decommissioning and dismantling

(where applicable)

For example disposal of chemical substances, pressure relief in pressure reservoirs.

G. Information for emergency situations

- Instructions to be followed in the event of an accident or breakdown. Where blockages can occur, the instruction handbook shall inform about measures to enable equipment to be unblocked safely.
- type of fire-fighting equipment to be used, where required.
- where required, instructions for rescuing trapped persons (for example by manually rotating the machine after release of the motor brake, starting the reversing movement, dismantling of parts of the machine).
- warning of possible emission or leakage of hazardous substances and, where possible, information about the means of abatement and their effects.

H. Information for lifting machinery

- Maximum load capacity;
- instructions that lifting of persons on lifting machinery is prohibited and other restrictions;

- report on static and dynamic testing carried out by the manufacturer (for detailed description of tests see Annex I 4.1.2.3 of the Machinery Directive).

2.2.3 Assembly instructions for partly completed machinery

Assembly instructions for partly completed machinery must include a description of the conditions to be met for correct incorporation of the incomplete machinery in the final machinery, without harming person's health and safety. Assembly instructions must be written in one of the official languages of the European Community, which is accepted by the manufacturer of the machinery in which the partly completed machinery will be incorporated.

2.3 Conformity assessment procedure

Conformity assessment is an umbrella term comprising a number of activities such as selection, determination (characteristics), evaluation (for compliance with relevant predefined or general requirements) and confirmation (by declaration of the manufacturer).

Any product placed on the market requires proof of compliance with the essential health and safety requirements. The procedure for providing this evidence is called conformity assessment.

Manufacturers are obliged to undertake conformity assessment before the first placing on the market of their machinery and it is prerequisite for the CE conformity marking. These procedures allow the manufacturer to prove conformity of his product with the essential health and safety requirements of the Directive. As a result of conformity assessment, the manufacturer can complete the EC Declaration of Conformity for his machinery declaring the product to conform to the provisions of the respective Directive(s). The Declaration of Conformity must be supplied together with the machinery.

2.3.1 Machinery not referred to in Annex IV

- Preparation of the technical file (see clause 2.1)
- A list of the internal measures implemented to ensure that all manufactured machines comply with the requirements of the Machinery Directive (for example checks, tests, internal production control).

Manufacturers are free to assign this task to a notified test and certification body (see clause 2.8).

2.3.2 Machinery referred to in Annex IV (high-risk machinery)

a) Machinery manufactured in accordance with harmonised standards

Where machinery is manufactured in accordance with the harmonised standards and provided that those standards cover all the relevant essential health and safety requirements, the manufacturer has to apply one of the following procedures (see clause 2.1), in addition to establishing the technical file:

- Internal production control to ensure compliance with the technical file and the provisions of the Machinery Directive or

- EC type-examination (Annex IX of the Machinery Directive) carried out by an external test lab or
- full quality assurance procedures of a certified quality assurance system (Annex X of the Machinery Directive) to ensure conformity of the machinery with the provisions of the Machinery Directive.

b) Machinery not manufactured or only partly manufactured in accordance with harmonised standards

Where machinery is not or only partly manufactured in accordance with harmonised standards or where the harmonised standards do not cover all the relevant essential health and safety requirements or if no harmonised standards exists for that type of machinery, the manufacturer has to apply one of the following procedures, in addition to the provision of the technical documentation (see clause 2.1):

- EC type-examination (Annex IX of the Machinery Directive) carried out by an external test lab or
- evidence of the internal measures implemented (checks, tests, internal production control etc.) to ensure that the machinery complies with the technical file (Annex VIII, clause 3, of the Machinery Directive).

2.4 Declarations

2.4.1 EC Declaration of Conformity

Any machine must be accompanied by an EC Declaration of Conformity in one of the official community language or languages of the member state where the machine is placed on the market and/or put into service.

The declaration supplied with the machinery must be an “original declaration of conformity” or the “translation of the original declaration of conformity” in which case the translation has to be accompanied by the original document.

With this declaration, the manufacturer certifies in writing that the machinery placed on the market by him is in conformity with the essential health and safety requirements of the Machinery Directive.

The original EC Declaration of Conformity must be kept available for at least 10 years following the date of placing on the market of the machine. The EC Declaration of Conformity must contain the following information:

2.3.3 Partly completed machinery

The documentation provided must allow verification of which of the provisions of the Machinery Directive apply and if they were satisfied. The following documents are required:

- specific technical file (see clause 2.1.3),
- assembly instructions (see clause 2.2.3),
- Declaration of Incorporation (see clause 2.4.2).

The assembly instructions and the Declaration of Incorporation must accompany the partly completed machinery until it is incorporated in the final machine. These documents will then be part of the technical file of the complete machine.

Manufacturers are free to assign this task to a notified test and certification body (see clause 2.8).

- Business name and full address of the manufacturer and, where appropriate, his authorised representative;
- name and address of the person authorised to compile the technical file; this person must be established in the Community;
- description and identification of the machinery, including the generic denomination, function, model, type, serial number and commercial name;
- a text expressing clearly that the machinery complies with all relevant provisions of the respective Machinery Directive and, where appropriate, a similar text indicating compliance with other directives and/or relevant provisions with which the machinery complies;
- where appropriate, a list of the harmonised standards applied;
- where appropriate, a list of the national standards and technical specifications used;
- place and date of the declaration;
- identity of the person authorised to draw up this declaration on behalf of the manufacturer or his authorised representative and this person’s signature (title, position within the company);

Requirements for placing machinery on the market in the European Economic Area (EEA)

- where appropriate, name and address of the notified test and certification body who has carried out the examination.

An example of the EC Declaration of Conformity is given in Annex 3.

2.4.2 Declaration of Incorporation (partly completed machinery)

Where machines or machine assemblies are incorporated into another machine or where a machine element is joined together with other element(s) to form one machine, this partly completed machinery (units, partial machines) must be accompanied by a Declaration of Incorporation issued by the manufacturer or his authorised representative.

The Declaration of Incorporation accompanying the machinery must be an “original declaration of incorporation” or the “translation of the original declaration of incorporation” in which case the original document must be attached to the translation of the declaration.

Language versions must be marked as “original declaration of incorporation” or “translation of the original declaration of incorporation”. The Declaration of Incorporation must contain the following information:

- Business name and full address of the manufacturer of the partly completed machine and, where appropriate, his authorised representative;
- name and address of the person authorised to compile the technical file; this person must be established in the Community;

- description and identification of the partly completed machinery, including the generic denomination, function, model, type, serial number and commercial name;
- a declaration that the essential health and safety requirements of this directive have been applied and satisfied and a sentence declaring that the relevant technical file has been compiled in accordance with Annex VII, Part B (see clause 2.1.3) and, where appropriate, a sentence declaring that the partly completed machinery is in conformity with other relevant directives;
- the obligation to transmit to national authorities, in response to a reasoned request, specific documentation of the partly completed machinery. This will also include the ways of transmission;
- a statement that the partly completed machinery must not be put into service unless the final machinery in which the partly completed machinery is to be incorporated is declared to be in compliance with the Machinery Directive;
- place and date of the declaration;
- identity of the person authorised to draw up this declaration on behalf of the manufacturer or his authorised representative and this person’s signature (title, position within the company);

An example of the Declaration of Incorporation is given in Annex 4.

The Machinery Directive does not specify the extent to which the requirements of the Machinery Directive which have been fulfilled have to be listed. In some cases it may be easier to indicate those provisions which were not satisfied. There are no particulars given as to the way this list should be drawn up. We recommend making out a separate list and attaching it as an annex to the Declaration of Incorporation.

2.5 CE-Marking

After signing the EC Declaration of Conformity certifying that all requirements of the Machinery Directive and other directives to be applied have been satisfied the manufacturer is entitled to affix the CE marking on his machinery.

The CE marking consists of the two letters CE and must be distinct, legible and indelible. The minimum height is 5 mm. This minimum height can be waived for small-scale machinery.



CE marking

The CE marking is mainly intended to provide a means of verification for the authorities of member states. It is not a quality or safety sign, but can rather be seen as a marking denominating admission of the machinery on the market or as a kind of machinery passport. It allows free circulation of goods within the domestic market.

For machines which are not within the scope of the machinery directive, CE marking indicates that the machinery conforms to the provisions of all other directives.

Consequently, it is the manufacturer's task to find out which directive is applicable for his technical product. In addition to the Machinery Directive, for example, also the EMC (electro-magnetic compatibility) directive could apply.

Directives are transposed into, for example, the following standards:

- EN 61000-6-4 “Electromagnetic compatibility – Generic standards – Emission standards for industrial environments”
- EN 61000-6-2 “Electromagnetic compatibility – Generic standards – Interference resistance in industrial environments”

The Machinery Directive requires the supervisory bodies of the member states to execute random checks also on machinery with CE marking in order to ensure compliance with the Machinery Directive.

Where machinery is found not to comply with the essential health and safety requirements of the Directive despite its CE marking, supervisory bodies are entitled to take appropriate measures ranging from prohibition of further placing on the market to imposing fines and withdrawal of the machinery from the market.

2.6 Interlinked systems (assembly of machinery)

2.6.1 Interpretation paper on “Assemblies of machinery” (Notice from the Federal Ministry of Labour and Social Affairs (BMAS) dated May 5th, 2011)

The EC Machinery Directive regulates the placing on the market of machinery and consequently the free movement of goods in the European Economic Area (EEA). In the Machinery Directive (MD) and the 9th provision of the Act on Consumer Products (Product Safety Act) as well as in the regulations transposing the Machinery Directive into German law, the term “machines/machinery” is defined in a broad sense of the word. According to the Machinery Directive, “machinery” can also be assemblies of machinery consisting of linked parts or components intended to work together and thus applies to all machinery commonly known as interlinked or complex machinery. Complex machinery would, for example, be machines for the production of corrugated board, production lines in paper converting, paper making machines and metal working equipment.

In the past there has always been doubt as to the characteristics applicable in order for machinery to be classified as “assembly of machinery” in the meaning of the Machinery Directive.

For guidance in the correct interpretation of the Machinery Directive, the Federal and State Ministers for Labour and Social Affairs in cooperation with the Professional Associ-

ations and the VDMA (German Engineering Federation) have worked out the following principles. The flow chart on page 24 demonstrates a procedure to adopt for determining whether machines are to be considered as an assembly of machinery in the meaning of the Machinery Directive. This German interpretation has been approved by the EC Commission.

2.6.2 Special requirements for interlinked machinery

According to Annex I, clause 1.2.4 of the Machinery Directive, in the case of machinery or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including emergency stop devices, do not only stop the machinery itself, but also all upstream and/or downstream machines and equipment if their continued operation is potentially dangerous. This then only applies to machinery or parts of machinery where interlinking is so pervasive that, in case one of the machines is stopped, the continued operation of the upstream or downstream equipment may lead to endangerment.

Consequently, where the degree of linking of machinery also requires the technical safety system to be interlinked, machines must be treated as an “assembly” functioning as an “integral whole” and must therefore comply with the provisions of the Machinery Directive including the CE marking.

The contents of the **interpretation paper** are listed in Items 2.6.3–2.6.5:

2.6.3 Definition of “assembly of machinery”

According to Article 2, Letter a, 4th dash in the Machinery Directive or Section 2, Number 2, Letter d, in the German machinery regulation (Maschinenverordnung), a “machine” is also:

- *assemblies of machinery [...] or partly completed machines [...] which, in order to achieve the same end, are arranged and controlled, so that they function as an integral whole.*

2.6.4 Applying the Machinery Directive to an assembly of machinery

According to the definition, it is particularly relevant that

1.

a production-related interlinking of machinery is created when

- the individual machines or partly completed machines are arranged together in an assembly in such a way that they are to be regarded as a closed unit (particular emphasis is placed on the contiguous set-up)

and

- the individual machines or partly completed machines work together as an assembly, (this means, for example, that their working together must be centred on a common objective, such as manufacturing a particular product)

and

- the individual machines or partly completed machines are operated as an assembly, i. e. they feature common or higher level functional controls, or a common control device

and

2.

the individual machines or partly completed machines function as an assembly from a safety system perspective, thus also forming a unit in this respect (safety-related interlinking of machinery).

This is the case when machines and/or partly completed machines are interconnected in such a way that an incident

which occurs in an integral unit of the system causes a hazard in another integral unit and safety-related measures must be implemented for this “assembly” to place all these integral parts into a hazard-free mode.

Annex I, Item 1.2.4.4 of the MD stipulates the following with respect to an assembly of machinery:

“Assembly of machinery:

In the case of machines or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery itself but also all related equipment, if its continued operation may be dangerous.”

If individual machines are **solely** interlinked by a common emergency stop device, this interlink on its own does not mean that these machines constitute an assembly of machinery.

If there is an interlink on a production and a safety-related level, this does constitute an assembly of machinery as defined in the MD. This assembly must meet the MD requirements.

When the term “assembly of machinery” is used in practice, the question often arises of how far such systems are subject to MD requirements as an assembly of machinery when they consist of complete industrial plants, such as smelting works, power stations or chemical plants. If we apply the different aforementioned decision steps to large industrial plants, the answer may often be “yes” to a production-related interlinking, but not from a safety-related perspective as a general rule. In this case, such plants are not subject to MD requirements as an assembly. However, it is possible that such large plants should be divided up into a number of individual sections which each correspond to an assembly of machinery.

The European Commission’s “Guide to application of the Machinery Directive 2006/42/EC” relates to the subject of complete industrial plants. In the third paragraph of Section 38, it stipulates that the term “assembly of machinery” does not necessarily apply to a complete industrial plant as a whole. It points out that, for the application of the Machinery Directive, such large installations can usually be divided into sections which may be considered as assemblies of machinery, such as raw material unloading and reception equipment, processing equipment and packaging and loading equipment.

2.6.5 Decision steps

The following decision steps and the flow chart (Assembly of machinery) on the next page are intended to help to evaluate to what extent a number of interlinked machines or partly completed machines constitute an assembly of machinery as per the MD.

Step 1

A production-related interlinking of machinery is characterised by the fact that the machines or partly completed machines are arranged as an assembly (with each unit constituting a part of a contiguous set-up), work together and are operated in such a way that they form a unit focused on achieving a common goal, such as the manufacture of a product. Such interlinked machinery exists when machines or partly completed machines are interconnected from a mechanical and/or control perspective and they feature common or higher level functional controls, or a common control device required for the production sequence. The common or higher level functional controls are thus essential to actually enable the machines or partly completed machines to work together on production-related level to achieve a purpose. If there is no such production-related interlinking of machinery, it is not an assembly of machinery as defined by the MD. An EC Declaration of Conformity is not required for the machine system as an assembly of machinery, but for the individual machines themselves only.

Step 2

If an incident occurs on a machine or a partly completed machine which may cause a hazard on another machine or partly completed machine in the system, safety measures need to be applied to the whole assembly. In this case, we talk of a safety-related interlinking of machinery which is characterised in that the safety of the whole assembly is guaranteed by a safety control applied to the whole assembly or by safety components which do not form part of this safety control system, such as fixed safety guards, and which guarantee safety for the assembly.

The risks which the machines or partly completed machines cause as they work together at their interfaces should also be taken into account in the assembly risk assessment. The European Commission's new "Guide to application of the Machinery Directive 2006/42/EC" covers this. In Section 38, it stipulates that the safety of an assembly of machinery depends not just on the safe design and construction of their constituent units but also on the suitability of the units and the interfaces between them. In particular, the interfaces resulting from constituent units need to be examined in this respect.

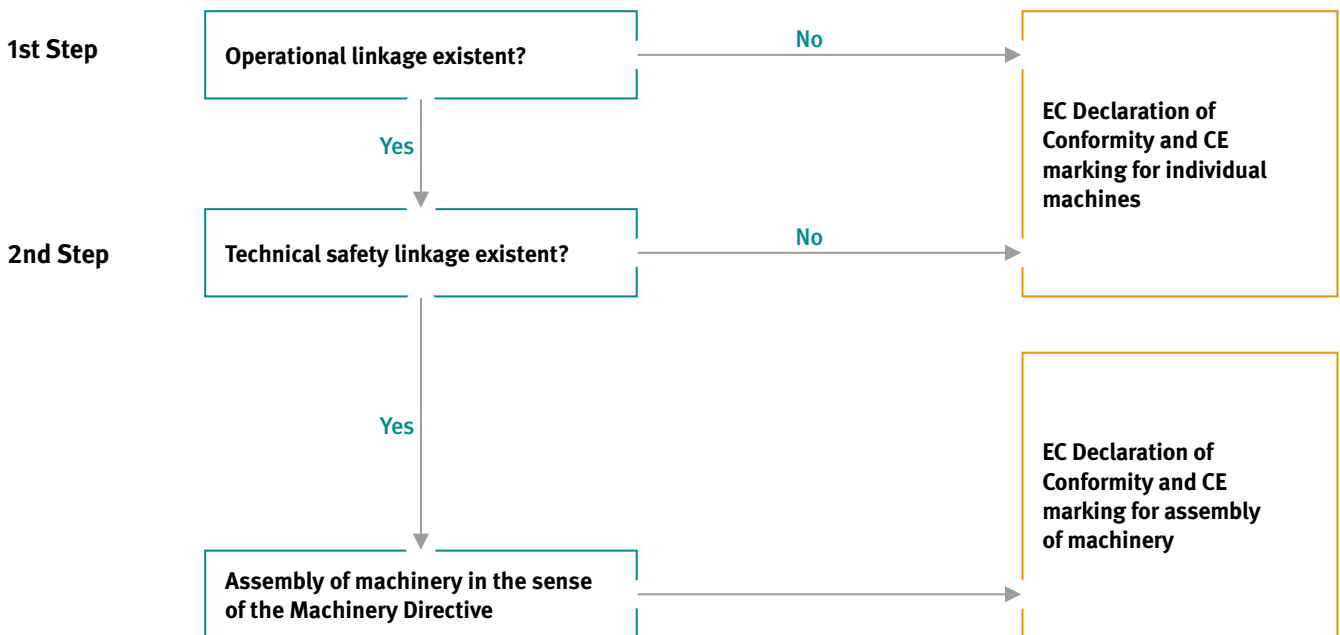
An EC Declaration of Conformity needs to be issued for the assembly of machinery (complete machinery) and accompany the complete machinery.

However, there is no safety-related interlinking of machinery if it is not possible for hazards in one of these machines to subsequently cause a hazard in the other machines or for new hazards to occur on these other machines when the individual machines work together on a production-related level. Machines connected to each other in this way can be regarded as individual machines.

The interfaces between the individual machines should also be taken into account in this respect. The machines can still be regarded as individual machines if the risk assessment considers the hazards occurring at the interfaces to be minor and the hazards can be eliminated or an acceptable level of risk can be achieved through simple technical and automatic protective measures, such as fixed safety guards, or by incorporating the individual machines into the security concept.

The following flow chart can be used to answer the question of how far the term "assembly of machinery" as defined by the MD can be applied to a group of machines.

Assembly of machinery



2.6.6 Examples of application

Gang stitchers

For the production of clamped brochures, gang stitchers are combined with trimmers. Trimmers are connected to the gang stitcher via a conveyor belt.

Physical connectivity

Is given by the arrangement of the components.

Functional linkage

Machines are assembled to produce a finished brochure. This meets the criteria for a common work result, i. e. a production unit.

Linking of control systems

Machine control is by one joint system, control engineering linking therefore exists.

Linking of technical safety

Risk assessment has revealed that high risks exist on the transfer points. When the guards on the trimmer feeder are opened, access to danger points on the trimmer and the gang stitcher is possible. The criterion “linkage of safety requirements” is therefore met.

Result

In the sense of the Machinery Directive this constitutes an assembly of linked machinery requiring the EC Declaration of Conformity for the assembly.



2.7 Market surveillance and product liability

2.7.1 Market surveillance

It is one of the main goals of the European Union to create and sustain a consistent and common domestic market. Existing trade barriers preventing the free movement of goods have been removed by harmonising the differing national requirements for technical products.

EC member states are obliged to enforce the Community law. Article 10 of the EC Treaty requires member states to take appropriate measures to ensure fulfilment of the obligations arising from this treaty.

Market surveillance is considered as an important instrument for enforcing the directives drawn up according to the New Approach. Market surveillance allows member states to take appropriate measures to monitor conformity of products with the specific directives and to take steps to eliminate shortcomings of conformity and, where appropriate, impose sanctions.

Member states are under the obligation to institute market surveillance authorities who monitor compliance of machines and partly completed machinery with the provisions of the Machinery Directive.

The principles of market surveillance are:

- It is an essential instrument for enforcement of the directives drawn up in accordance with the New Approach.
- The aim is to ensure that the requirements of the relevant directives are satisfied throughout the entire Community. Every European citizen within the domestic market is entitled to an equal level of protection from hazards, irrespective of where a product has been manufactured. Market surveillance also plays an important role for stakeholders in the respective industries as it provides a basis for action against unfair competition.
- Member states must institute or appoint authorities competent for market surveillance. Such authorities must be provided with the resources and mandates necessary for their monitoring task, it is within their responsibility that the personnel involved are adequately qualified and carry out their tasks with due professional diligence, that they are independent and act without discrimination and with due respect of proportionality.

In Germany, the Machinery Directive has been transposed into German law by the 9th Ordinance (Machinery Ordinance) to the Product Safety Act. According to article 8, item 2 of this Act, the competent authorities must ensure effective monitoring of the placing on the market of products and also of the products placed on the market. This takes account a central idea of the New Approach which regards market surveillance as an essential instrument for enforcing the new directives in member countries.

The respective acts can impose sanctions for infringement of the regulations for placing on the market of products. There are a number of possibilities for penalties which must, according to the Machinery Directive, be “effective, proportionate and dissuasive”.

Authorities can impose sanctions ranging from compensation of damage up to, by virtue of their sovereign functions, the prohibition of the product on the market, depending on which legal basis is applied.

2.7.2 Safeguard clause

The New Approach Machinery Directive contains provisions for a kind of safeguard clause obliging member states to restrict or prohibit the placing on the market and putting into service of hazardous products or to take measures to withdraw them from the market.

This safeguard clause basically applies to products which

- come under the New Approach directives,
- bear the CE marking and
- are rated as potentially high-risk products by member states

even if they are properly constructed, assembled and maintained and used as intended.

The safeguard clause is applied to national measures which

- restrict or prohibit the placing on the market of a product or withdraw it from the market,
- relate to products produced in batches or series and are legally binding.

Requirements for placing machinery on the market in the European Economic Area (EEA)

Member states must immediately inform the European Commission of any such measure adopted under the safeguard clause. They must also indicate the reasons for their decision and provide respective evidence. If the European Commission agrees that such measures are justified, they will immediately inform the other member states so that they can also start respective action in their countries.

2.7.3 Product liability

Since 1985 a Product Liability Directive has been in effect in the European Economic Area (EEA), which was transposed into Germany law by the Product Liability Act in 1990.

All machine manufacturers in the EEA are subject to the European Product Liability Directive. This directive does not overrule the legal provisions on product liability existing in the member states, but is rather intended to supplement their individual liability regulations (in Germany for example this would be the German Civil Code).

Product liability is intended to enable users to claim compensation for damage caused by a defective product. Users shall be compensated for any damage, for example personal injury, caused by, for example, an improperly designed product. This includes for example reimbursement of travelling expenses required for clinical treatment or even compensation for permanent reduction in earning capacity. By holding producers liable for damage resulting from defective products, it is expected that they will not place defective products on the market in the first place.

Manufacturers are liable for their products regardless of fault and it is therefore not necessary to prove negligence or fault of the producer, the only criterion is whether the defective product was the cause for the damage. By abandoning the principle of personal fault, producer's product liability has been considerably tightened.

Producer liability without producer fault does however not mean that producers are liable for any damage, their liability is restricted to those cases where a product is defective and where such defectiveness is the cause of the damage.

According to the Product Liability Act, a product is defective if it does not provide the safety which a person is entitled to expect, taking into account all circumstances that can be expected, in particular

- the presentation of the product,
- the use of the product,
- the time when the product was put into circulation.

The circumstances to be expected are determined by the state of the art of science and technology. The product liability directive stipulates that producers are liable only if the state of scientific and technical knowledge at the time when the product was put into circulation was such that the defect could have been discovered.

According to the principles established in the directive, producer's liability ends at the date of placing on the market of the product. It remains to be seen if future court ruling will lead to producer's liability being extended beyond the date of placing on the market of the product.

In any case, the principles established by case-law continue to apply, i. e. the producer is also liable if he fails to meet his obligation to observe the product, attributable to his fault or negligence.

The directive specifies the category of persons who are considered as manufacturers and therefore can be held liable. They are the manufacturers of the finished product, the manufacturers of a component or part or any person who presents himself as the producer by putting his name, trade mark or similar on the product. Liability is also extended to any person who imports the product into the Community as well as suppliers. Suppliers can be exempt from producer's liability only if they can inform the injured person of the producer or, for example, the person who supplied them with the defective product.

Producers are not allowed to limit or exclude the liability arising from the Product Liability Act.

2.8 Test and Certification Body Printing and Paper Converting

2.8.1 Test and certification system provided by the professional association (DGUV Test)

The professional associations in Germany have established a common test and certification system (DGUV Test) for testing and certification of products and quality assurance systems.

Taking part in this system are the testing and certification bodies representing the specialist divisions and areas of the individual professional associations and the Institute for Occupational Safety and Health (IFA) as well as the Institute for Work and Health (IAG).

The Test and Certification Body of the Technical Committee Printing and Paper Converting also takes part in the DGUV Test system. Their scope of testing includes printing and paper converting machines, paper making and finishing machines as well as air humidifying equipment and office machines.

The Test and Certification Body Printing and Paper Converting take it as their foremost responsibility to assist and support manufacturers of printing and paper converting machinery and of paper making and finishing machines in creating the requirements to demonstrate conformity with the directives. We issue the GS mark for ready-to-use consumer items.

The DGUV Test sign is issued where tests have also been carried out on special aspects of a machine, such as emissions from sheet-fed offset printing presses or optimised air humidification. The DGUV Test sign is also issued for partly completed machines.

We also issue ET (EuroTest) marks for tested machinery.

Furthermore, the Test and Certification Body Printing and Paper Converting is a European notified body identified by their code number 0739.

They are therefore entitled to test and certify within their scope the machines listed in Annex IV of the Machinery Directive (high-risk machines).

2.8.2 GS sign, DGUV Test sign

As the CE marking is not a quality sign, there is still further need to provide a test sign signalling to the user that the product has been tested with regard to health and safety

by an independent test body and that the GS or DGUV Test sign as well as the ET mark was issued.

GS or DGUV Test signs may still be affixed on machines in addition to the CE marking; however, care must be taken that the sign does not overlap the CE marking and leaves it clearly visible.

For testing the machine and awarding test signs, the notified body is entitled to survey the production.



DGUV Test sign

This system of production control underlines the high quality of the sign awarded to users of certified machines as this ensures that manufacturers produce the certified machines in compliance with the machinery for which type examination has been carried out.

In addition, the user plant is inspected prior to certification in order to make sure that production in compliance with the type-examination machinery is possible over the long term due to its internal quality management.

2.8.3 EuroTest mark (ET mark)

The Test and Certification Body Printing and Paper Converting is a member of the EuroTest Cooperation which combines the professional knowledge of experts of 12 organisations from various European countries (e.g. the United Kingdom, Germany, Poland, Sweden, the Czech Republic, Slovakia, Italy and Romania).

The requirements for awarding the ET mark are identical to those for the GS sign. However, the ET mark also documents that the Test and Certification Body Printing and Paper Converting is a European notified body jointly working together with other European notified bodies.



ET sign

2.9 Placing on the market of new units to be incorporated in existing machines

When units or machine parts are placed on the market which are to be incorporated in existing machines, for example varnishing units, printing units, unwinds, splicers, such units must conform to the provisions of the Machinery Directive. They must be provided with a Declaration of Incorporation identifying the standards applied and giving instructions for adequate assembly as they

cannot operate as stand-alone machines and are possibly safeguarded only after incorporation of the machinery.

The existing machine needs not be upgraded to conform to the Machinery Directive level and needs not be provided with a (new) CE marking.

2.10 Second-hand machines

2.10.1 Import of second-hand machines into the European Economic Area (EEA)

Second-hand machines which are imported from third countries, i. e. from countries other than the European Economic Area, must be in conformity with the EC Machinery Directive. In this case it is recommended to assign a notified test and certification body with the task of certifying.

The European Economic Area comprises all EC member countries and Norway, Iceland and Liechtenstein.

2.10.2 Placing on the market of second-hand machinery from EEA countries

a) Unchanged or reconditioned second-hand machines

The same provisions apply as when placing the product on the market for the first time. Unchanged or reconditioned second-hand machines are allowed to be placed on the market for a second time only if their technical safety conforms to the requirements existing at the time of their first placing on the market.

If their first placing on the market was before 1995, they must satisfy the accident prevention regulations valid at that time (for example VBG 5 and VBG 7i). For machines which were placed on the market for the first time after 31.12.1994, the provisions of the Machinery Directive apply.

Reconditioned machinery is existing machinery which has been technically modified so that it can operate as intended. Unchanged machinery would principally be resold directly without further modification.

The Council directive concerning the minimum safety and health requirements for the use of work equipment by workers at work must also be complied with. In Germany, this directive has been implemented by the Ordinance on Industrial Safety and Health stipulating that users may also be required to recondition old existing machines, where appropriate.

As far as printing and paper converting is concerned, all machines conforming to the accident prevention regulations for power-operated work equipment (VBG 5:1985) and for printing and paper converting machines (VBG 7i:1985) also comply with the Council Directive for the use of work equipment, except for guillotines, sheet-fed screen printing presses with manual feeding between table and screen, hand-fed label punches and platen machines for cutting and creasing.

Information sheets specifying retrofitting requirements for these types of machines (with the exception of handfed label punches) can be obtained from the respective Professional Association "Energie Textil Elektro Medien-erzeugnisse".

b) Interpretation of “significant modifications” in relation to used machines (Announcement of the BMAS of 09.04.2019)

Each change to a used or new machine which may adversely affect the protection of goods legally protected under the German Act on Making Products Available on the Market (ProdSG) first needs to be analysed with regard to its effect on safety-relevant aspects.¹ Such changes may be caused by aspects such as power increases, changes to functions or a change to designated use (due to factors such as a change of auxiliary, operating or raw materials, a structural modification or modifications to the safety system). This means that, each time, there is a need to establish if the change to the (new) machine poses new hazards² or has increased an existing risk³. There are three different scenarios in this respect:

1. There is no new hazard or increase to an existing risk, meaning that we can continue to regard the machine as safe.
2. Although there is a new hazard or increase to an existing risk, the existing protective measures before modification are still adequate or suitable to ensure safe operation.
3. There is a new hazard or increase to an existing risk and the protective measures existing on the machine before the change are not adequate or suitable to ensure safe operation.

No additional protective measures are required for the modified machines in scenarios 1 or 2. In contrast, modified machines in scenario 3 must systematically undergo a further risk assessment to determine whether the change is significant or not.

In the process, it should be determined whether it is possible to make the modified machine safe again with simple safety devices while also verifying that the simple safety device eliminates the risk or at least minimises it to an adequate extent. If this is the case, the change can generally be regarded as non-significant.

A simple safety device as referred to above may consist of a fixed safety guard, for example. Simple safety devices also include movable safety guards and other safety

systems which do not interfere significantly with the machine’s existing safety system controls. This means that these safety devices only connect to signals which the existing safety controls are already designed to process or that the dangerous machine function is merely brought safely to a standstill, independent of the existing safety controls.

The replacing of components on the machine with identical components or components with an identical function and an identical safety level as well as the fitting of safety devices which increase the machine’s safety level and otherwise do not provide any additional functions are not regarded as a significant change.

Note:

Irrespective of these exceptions, other statutory regulations may require the employer who provides the machine to their employees as work equipment to establish additional protective measures.

In general, a risk assessment must be carried out in line with Section 3 of the German ordinance on industrial safety and health⁴ (BetrSichV) after any type of change to machines, not just significant ones. This is one of the operational work safety obligations applicable to the user of a machine or system as work equipment. Measures may be required as a result of the risk assessment, particularly technical measures, to ensure that employees are provided with safe work equipment. It should be verified whether information on the safe operation of machines, such as the operating instructions, needs to be adapted (cf. Section 12 BetrSichV).

¹ This analysis may be carried out based on the procedures outlined in EN ISO 12100 Safety of machinery – General principles for design – Risk assessment and risk reduction, for example.

² MD, Annex I, Item 1.1.1 a): ‘hazard’ means a potential source of injury or damage to health.

³ MD, Annex I, Item 1.1.1 e): ‘risk’ means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation.

⁴ Ordinance on safety and health protection in the use of work equipment (Ordinance on industrial safety and health – BetrSichV).

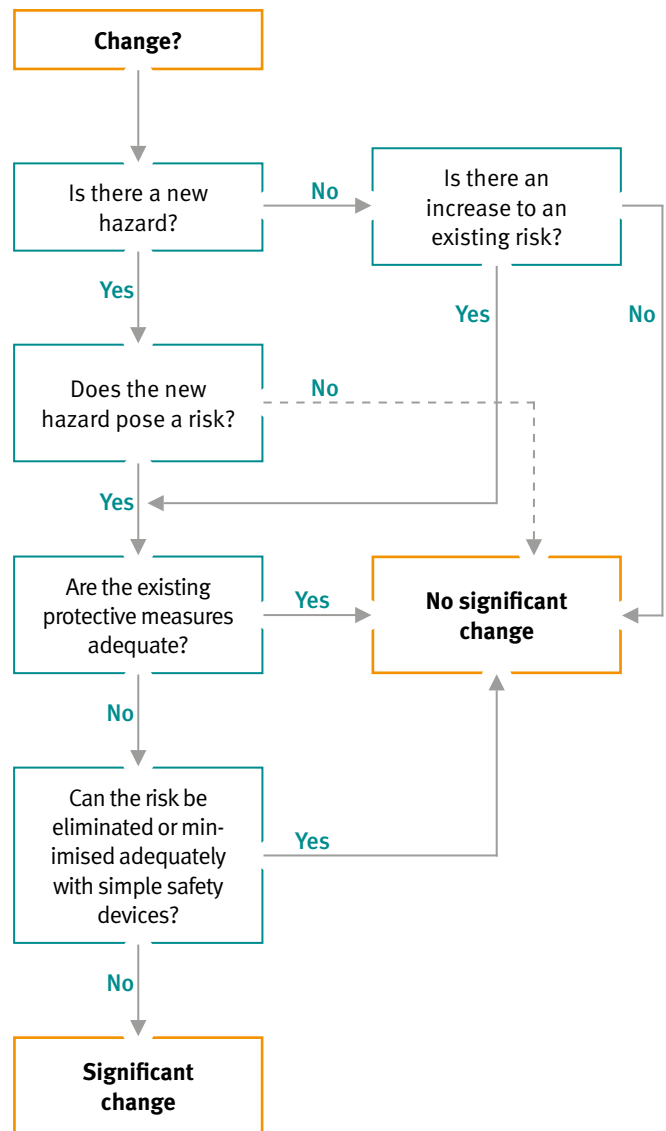
Requirements for placing machinery on the market in the European Economic Area (EEA)

Conclusion

Changes to a machine/assembly of machinery⁵ may have the following effects:

- 1 The machine is still safe after the change without the need for additional protective measures.
 → There is **no** significant change.
- 2 The machine is no longer safe after the change without additional protective measures. The new hazard or the increased risk can be eliminated or at least minimised to a sufficient extent with simple safety devices.
 → There is **no** significant change.
- 3 The machine is no longer safe after the change without adding additional protective measures and it is not possible to reduce risk sufficiently with simple safety devices.
 → **There is a significant change.**

The following flow chart helps to decide whether there is a significant change or not:



Flow chart: Significant change to the machine

Significantly changed machines

A significantly changed machine is treated as a completely new machine. The provisions in the German Act on Making Products Available on the Market and the 9th Ordinance on Product Safety Act must be applied.

This means that the person responsible for the significant change becomes the manufacturer and thus must comply with the manufacturer's obligations as per the German Act on Making Products Available on the Market and the 9th Ordinance on Product Safety Act. The manufacturer must then ensure that the significantly changed machine complies with the fundamental safety and health protection requirements as per Annex I of the MD. They shall carry out the conformity

assessment procedure for the machine concerned and, in particular, shall produce the mandatory technical documentation with which they can provide evidence that the conformity assessment procedure has been carried out.

The manufacturer will also supply the operating instructions and, where necessary, provide the significantly modified machine with warning notices regarding the remaining risks which cannot be minimised further due to the current standard of technical protective measures.

Finally, the manufacturer issues the EC Declaration of Conformity, attaches it to the machine and affixes the CE marking to the significantly changed machine.

⁵ Interpretation paper on 'Assemblies of machinery' – Notice from the Federal Ministry of Labour and Social Affairs (BMAS) dated 05/05/2011, IIIb5-39607-3 – GMBI 2011, p. 233

Assembly of machinery

The above principles apply to the modification of an assembly of machinery. If the change in an assembly of machinery (e. g. complex production plant or integrated production system) only exceeds a partial range, the

extent to which this has an effect on the assembly as a whole (machinery as a whole) must be examined. If this change itself and its effects on the whole are to be assessed as material, then there is a material change in the assembly of machinery.

2.11 Machinery imported directly by operators

New machines which the operator purchases and imports directly from abroad (non-intra-European trade) must also comply with the Machinery Directive requirements.

In the case of a direct import, it is the operator or the machine retailer who is responsible for the machine's safety, regardless of whether the manufacturer has issued an EC Declaration of Conformity or not.

When drawing up the sales contract, it is therefore important to specify that the machine must comply with the Machinery Directive and that the manufacturer must meet the specifications in the directive.

The operator must demonstrate that the machine complies with the Machinery Directive. If necessary, the operator must also issue a declaration of conformity.

If any defects are apparent on the machine, due to an accident or inspection by authorities, for example, the operator must eliminate the defects and possibly compensate for damages as per the German Product Liability Act. The same applies to the machine retailer who imports the machines into the EU.





3

Annex

Annex 1: Definitions

Annex 2: Requirements for placing on
the market of machinery

Annex 3: Sample EC Declaration of Conformity

Annex 4: Sample EC Declaration of Incorporation

Annex 5: List of Standards

Brochures available in Germany



3 Annex

Definitions

Conformity

Conformity with the essential health and safety requirements of the respective directives.

Commission

Is an organ of the European Community establishing EC Directives.

Harmonised standard

This is a non-binding technical specification mandated by the Commission, which was established and adopted by a European standardising body (CEN, CENELEC or ETSI) and published in the Official Journal of the European Union. Harmonised standards allow presuming conformity of the products with the essential health and safety requirements laid down in the Machinery Directive (presumption of conformity).

Interchangeable equipment

A device which, after a machine or tractor has been put into service, is assembled with that machinery or tractor by the operator himself in order to modify or extend its function in so far as this equipment is not a tool.

Manufacturer

Means any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by the Machinery Directive and who is responsible for conformity of the machinery or partly completed machinery with the Machinery Directive with a view to its placing on the market, under his own name or trademark or for his own use.

Where a manufacturer in the above-mentioned sense does not exist, any natural or legal person who places on the market or puts into operation a machine or partly completed machinery covered by the Machinery Directive is regarded as the manufacturer.

Machinery

- An assembly of linked parts or components at least one of which moves, including, where applicable, actuators, control and power circuits etc., joined together for a specific application such as the processing, handling and treatment of material.
- An assembly 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 on site or to sources of energy and motion.
- An assembly referred to in the first and second indents, ready to be installed which is able to function only if mounted on a means of transport or if installed in a building or a structure.
- An assembly of linked parts or components referred to in the first, second and third indent or partly completed machinery which, in order to function together, are arranged and controlled in such a way 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 for lifting and whose only power source is directly applied human force.

Requirements for placing machinery on the market in the European Economic Area (EEA)

Notified body

Bodies from member countries which are registered with the Commission and are authorised to test machinery listed in Annex IV of the Machinery Directive. They are registered under a code number.

Safety component

is a component,

- which serves to fulfil a safety function,
- which is placed on the market independently,
- the failure and/or malfunction of which endangers the safety of persons, and
- which is not necessary for the function of the machine or which may be substituted by components normally used for the machinery to function.

A list of safety components is set out in Annex V of the Machinery Directive, which may be updated in accordance with Article 8, clause 1(a).

Partly completed machinery

This means an assembly which is almost machinery but which cannot perform a specific function in itself.

A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or partly completed machinery or equipment in order to form machinery in the sense of the Machinery Directive.

Requirements for placing machinery and safety components on the market

Machinery and partly completed machinery (not tools or spare parts)	Partly completed machinery (cannot function on their own)	Safety component
To be manufactured in accordance with Annex I of the Machinery Directive	To be manufactured in accordance with Annex I of the Machinery Directive as far as possible	To be manufactured in accordance with Annex I of the Machinery Directive
Technical documentation	Technical documentation	Technical documentation
Instruction handbook	Assembly instructions*	Instruction handbook
EC Declaration of Conformity	Declaration of Incorporation	EC Declaration of Conformity
CE marking	–	CE marking

* Although the Machinery Directive does not explicitly require instruction handbooks for partly completed machinery, it is recommended to draw up such a handbook so as to enable the manufacturer of the machine into which the partly completed machinery is to be incorporated, to add it to the technical file of his machinery.

Sample 1: EC Declaration of Conformity

Company name and full address:

EC Declaration

of Conformity according to EC Machinery Directive 2006/42/EC, Annex II A

We do hereby declare that the machinery cited below

Generic denomination, type serial number, trade name

conforms to the requirements of the following directive(s):

Machinery Directive	2006/42/EG
EMC Directive	2014/30/EG

....

Harmonised standards applied:

EN ISO 12100
EN 1010-1
EN 1010-2
EN 1010-3
EN 1010-4
EN 1010-5
EN ISO 13849-1
EN 60204-1

....

National standards and technical specifications applied:

.....

Authorised representative for compiling the technical file:

(place, date, signature))

(name of the undersigned, legal position)

Sample 2: EC Declaration of Conformity

(Type-examination carried out by the Test and Certification Body Printing and Paper Converting of the Germany Statutory Accident Insurance)

Company name and full address:

EC Declaration

of Conformity according to EC Machinery Directive 2006/42/EC, Annex II A

We do hereby declare that the machinery cited below

Generic denomination, type serial number, trade name

conforms to the requirements of the following directive(s):

Machinery Directive	2006/42/EG
EMC Directive	2014/30/EG

....

Harmonised standards applied:

EN ISO 12100
 EN 1010-1
 EN 1010-2
 EN 1010-3
 EN 60204-1
 EN ISO 13849-1

....

National standards and technical specifications applied:

.....

Authorised representative for compiling the technical file:

 (place, date, signature)

 (name of the undersigned, legal position)

The type-examination for compliance with the requirements of the Machinery Directive was carried out by the Test and Certification Body Printing and Paper Converting, Rheinstrasse 6–8, D-65185 Wiesbaden/Germany. This test body is a notified body in compliance with Annex XI of the EC Machinery Directive.

Sample: EC Declaration of Incorporation

Company name and full address:

EC Declaration

of Conformity according to EC Machinery Directive 2006/42/EC, Annex II B

We do hereby declare that the partly completed machinery cited below:

Generic denomination, type serial number, trade name

**conforms to the essential requirements* of the following directive(s),
as far as feasible for the scope of the delivery:**

Machinery Directive 2006/42/EC, clause ... *

**We declare that the relevant technical documentation for this partly completed machinery
has been compiled in compliance with Annex VII Part B and that we undertake to transmit this
technical documentation to the national authorities on request in digital form.**

**This partly completed machinery must not be put into service until the final machinery into
which it is to be incorporated has been declared in conformity with the Machinery Directive.**

Authorised representative for compiling the technical file:

_____ (place, date, signature)

_____ (name of the undersigned, legal position)

* Provisions can be listed in an Annex

List of Standards

Title of the standards cited in the text

- **EN ISO 12100**
Safety of machinery – Basic concepts, general principles for design, Part 1: Basic terminology, methodology
- **EN ISO 13849-1**
Safety of machinery – Safety-related parts of control systems, Part 1: General principles for design
- **EN 62079**
Preparation of instructions – Structuring, content, presentation
- **EN 1010-1**
Safety of machinery – Technical safety requirements for the design and construction of printing and paper converting machines – Part 1: Common requirements
- **EN 1010-2**
Safety of machinery – Technical safety requirements for the design and construction of printing and paper converting machines – Part 2: Printing and varnishing machines including pre-press machinery
- **EN 1010-3**
Safety of machinery – Technical safety requirements for the design and construction of printing and paper converting machines – Part 3: Cutting machines
- **EN 1010-4**
Safety of machinery – Technical safety requirements for the design and construction of printing and paper converting machines – Part 4: Bookbinding, paper converting and finishing machines
- **EN 1010-5**
Safety of machinery – Technical safety requirements for the design and construction of printing and paper converting machines – Part 5: Machines for the production of corrugated board and machines for the conversion of board and corrugated board
- **EN 13023**
Noise measurement methods for printing, paper converting, paper making machines and auxiliary equipment – Accuracy grades 2 and 3
- **EN 60204-1**
Safety of machinery – Electrical equipment of machines, Part 1: General requirements
- **EN 61000-6-4**
Electromagnetic compatibility, Part 6–4: Generic standards – Emission standard for industrial environments
- **EN 61000-6-2**
Electromagnetic compatibility, Part 6–2: Generic standards – Immunity for industrial environments
- **prEN ISO 12643-1**
Graphic technology – Safety requirements for graphic technology equipment and systems – Part 1: General requirements
- **prEN ISO 12643-2**
Graphic technology – Safety requirements for graphic technology equipment and systems – Part 2: Press equipment and systems
- **prEN ISO 12643-3**
Graphic technology – Safety requirements for graphic technology equipment and systems – Part 3: Binding and finishing equipment and systems
- **prEN ISO 12643-4**
Graphic technology – Safety requirements for graphic technology equipment and systems – Part 4: Converting equipment and systems
- **prEN ISO 12643-5**
Graphic technology – Safety requirements for graphic technology equipment and systems – Part 5: Stand-alone platen presses

Sources of supply

European Standards

Beuth Verlag GmbH
Burggrafenstraße 6
D-10787 Berlin
Telephone + 49(0)30 2601-0
Fax + 49(0)30 2601-1260
www.beuth.de

Standards search

<http://www.kan.de>

Machinery Directive 2006/42/EC

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:157:0024:0086:en:PDF>

Information about standards which satisfy EC directives

https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/machinery-md_en

Note: Unlike in the past, future publications will not appear as a consolidated list; instead, only the changes compared to the previous document will be described.

Application guidelines for the Machinery Directive

https://www.bmas.de/SharedDocs/Downloads/DE/Arbeitsschutz/leitfaden-fuer-anwendung-maschinenrichtlinie-2006-42-eg.pdf?__blob=publicationFile&v=4

Info sheets of the Testing and Certification Body Printing and Paper Converting

Telephone +49 (0)221 3778-8219
Email pruefstelle-dp@bgetem.de

Berufsgenossenschaft Energie Textil Elektro Medienerzeugnisse – Accident Insurance Institution

Every employer is by law a member of the Berufsgenossenschaft responsible for his particular branch of industry. The Berufsgenossenschaft is headed by the representatives assembly and the executive board where both employers and employees share an equal part.

The tasks of the Berufsgenossenschaft are:

1. Prevention of accidents and occupational diseases and protection of workers from health hazards at work
2. Rehabilitation of persons injured by accidents
3. Financial aid

To preserve the health and lives of the insured is the principle task of the professional associations. As accident insurance institution they have been entrusted by law with the first and foremost responsibility to prevent accidents and occupational diseases. Their Technical Inspectorates supervise compliance with accident prevention regulations and advise member companies and their employees on all matters of safety at the workplace.

Next to accident prevention, the second major task of the Berufsgenossenschaften is medical rehabilitation to restore the health of persons injured by accidents. Berufsgenossenschaften run their own accident hospitals. Rehabilitation advisors assist injured persons to reintegrate into the workforce.

Medical and occupational rehabilitation is further supported by granting financial aid to the injured person. The idea is to avoid undue financial losses for anyone not being able to fulfil his job on the grounds of an occupational accident or disease.

For any further information on safety at the workplace, please do not hesitate to contact your Berufsgenossenschaft.

**Berufsgenossenschaft
Energie Textil Elektro
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www.bgetem.de

Order no. MB049e

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in the workplace are available at
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 de.linkedin.com/company/bgetem

 www.bgetem.de/ganzsicher