

The European Association of the Machine Tool Industries

Where manufacturing begins



Guidelines

for CE marking on
metalworking milling machines

08/2017

Objectives of the guide

Machinery and equipment which are bound by specific European Directives cannot be placed on the single market unless they bear CE marking. CE marking affixed on a product indicates that the product complies with all relevant essential requirements (e.g. health and safety requirements) of the applicable Directive(s).

However, market surveillance in the EU often fails to prevent the entry of non-compliant imported machinery into the internal market and/or the circulation of non-compliant European machinery in Europe. Machines which do not meet essential health and safety regulations threaten health and safety in the workplace and put workers' lives in danger.

Moreover, manufacturers and suppliers who do not comply with European regulations benefit from reduced production costs and gain an unfair comparative advantage in the market.

This distorts competition and undermines the competitiveness of European manufacturers who invest a significant amount of their resources in the development of products with high safety standards meeting European regulations.

Cases of non-compliance may occur due to lack of information (or misinformation) of producers who fail to meet the relevant

essential requirements or due to deliberate infringements by producers who want to unfairly cut their production costs.

Improving EU market surveillance requires better communication towards economic operators on EU regulations, standards and conformity assessment procedures to improve ex-ante mechanisms designed to ensure compliance with EU law. Ex-post mechanisms allowing market surveillance authorities to check compliance should also be strengthened.

CECIMO believes that effective market surveillance requires close cooperation between economic operators, customs authorities and market surveillance bodies.

In line with this view, the present guide aims to contribute to the ongoing work led by the European Commission to enhance market surveillance in the internal market, under the New Legislative Framework.

We hope that this guide will be a valuable source of information for manufacturers, sellers and users of machine tools as well as customs authorities to detect non-compliant products in the internal market. Better functioning market surveillance will contribute to creating a more secure working environment for workers and a more competitive European industry.

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Verifying the validity of the declaration of conformity

The declaration of conformity indicates the EU Directives which apply to milling machines and to which the equipment complies with, must include at least the following:

EU Directives which apply to milling machines

The machine shall comply with all the applicable Directives and these shall be mentioned in the declaration of conformity. The infringement of a single Directive results in the non-conformity of the machine to EC requirements.

Therefore, it is of utmost importance to specify which Directives apply to each machine and to conduct a declaration of conformity that includes all the necessary information.

Directives which apply to milling machines include:

- Machinery Directive (2006/42/EC)
- Electromagnetic Compatibility Directive (2014/30/EU)

Additionally, for the conformity assessment the manufacturer can refer to the harmonised standards or other technical standards, such as:

- ISO/FDIS 16090-1 - Machine tools safety - Machining centres, Milling machines, Transfer machines - Part 1: Safety requirements¹.

- EN 12417:2001+A2:2009 Machine tools - Safety - Machining centres.
- EN 12417:2001+A2:2009/AC:2010.
- EN 13128:2001+A2:2009 Safety of machine tools - Milling machines (including boring machines).
- EN 13128:2001+A2:2009/AC:2010.
- EN ISO 12100:2010 safety of machinery - General principles for design - Risk assessment and risk reduction.
- EN 60204-1:2006/A1:2009 Safety of machinery - Electrical equipment of machines - Part 1: General requirements.
- IEC 60204-1:2005/A1:2008.
- EN 60204-1:2006/AC:2010.
- EN ISO 13849-1:2015 Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design.
- EN ISO 4413:2010 Hydraulic fluid power - General rules and safety requirements for systems and their components
- EN ISO 4414:2010 Pneumatic fluid power - General rules and safety requirements for systems and their components.
- EN ISO 14120:2015 Safety of machinery - Guards - General requirements for the design and construction of fixed and movable guards.
- EN ISO 13857:2008 Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs.

¹ ISO 16090-1 is expected to be published in September 2017. At the date of publication of these Guidelines this standard has not been adopted as a European standard as is not included in the list of harmonised standards under the Machinery Directive (2006/42/EC). The presumption of conformity is only given by EN 13128, which is included in the above-mentioned list of harmonised standards.

- EN ISO 13855:2010 Safety of machinery
- Positioning of safeguards with respect to the approach speeds of parts of the human body.

Compliance with harmonised standards provides a presumption of conformity with the corresponding requirements of legislation. Manufacturers, other economic operators or conformity assessment bodies can use harmonised standards to ensure and/or demonstrate that products or processes comply with relevant EU legislation. Harmonised standards are published in the Official Journal of the EU².

The EC Declaration of Conformity

If the machine is CE marked and put on the market, the Declaration of Conformity shall accompany the machine and should be presented to market surveillance authorities. The EC Declaration of conformity must be provided in the language of the country where the machine is to be used.

It is the responsibility of the manufacturer or his authorized representative to draw up and sign an 'EC declaration of conformity' (DoC) proving that the product meets the requirements.

The DoC must include:

- Business name and full address of the manufacturer and, where appropriate, his authorised representative (the business name and full address of the manufacturer shall be the same as those typed on the machine). The manufacturer is not obliged to have an authorized representative, although should he

choose to do so, the person must be established in the European Community and the business name and full address of this authorized representative must appear.

- Name and address of the person authorised to compile the technical file, who must be established in the Community. The name and address of the person authorized to compile the technical file must be a natural or legal person established in the EU, it can be the manufacturer himself (if established in the EU).
- Description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;
- A sentence expressly declaring that the machinery fulfils all the relevant provisions of the Machinery Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies;
- Where appropriate, a reference to the harmonised standards or to other technical standards and specifications used;
- If relevant, the identification number of the Notified Body; and a legally binding signature on behalf of the organization.

The purpose of this data is to allow surveillance authorities to communicate with the manufacturer. Thus, the business address shall be stated in full. Simply stating the name of the area or the postcode does not suffice.

² The latest list of harmonised standards can be consulted in the following European Commission website: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

EC DECLARATION OF CONFORMITY

[Business name and full addresses of the manufacturer OR name and address of the manufacturer's authorised representative established in the EC and the business name and address of the manufacturer]

We hereby declare that the product:

[Generic denomination, Function, Model, Type, Serial number, Commercial name]

Is in accordance with:

[Machinery Directive]

[other Directives which apply³]

Is in accordance with:

[Harmonised standards applied]

NB: The application of harmonised standards is not obligatory. However, any harmonised standards that have been employed to conform to the Directive should be mentioned.

The following person is authorized to compile the technical file:

[Name, function, business address]

Place and date of the declaration:

Name, signature, function:

[Clear identification of the person empowered to sign on behalf of the manufacturer or its authorised representatives, plus the person's position]

³ The Declaration of Conformity should not refer to the Low Voltage Directive (LVD). The safety requirements of the Low Voltage Directive are described in the section 1.5.1 of Annex I to the Machinery Directive. The emissions requirements of the Electromagnetic Compatibility Directive are applicable in addition to those of the Machinery Directive.

CONFORMITY DECLARATION

According to the European Machine Directive 2006/42/EC, Enclosure IIA

We hereby declare that the machine

Manufacturer/Distributor: John Doe
123 Anywhere Street
Anytown, State 12345
Machine designation: Milling Machine
Machine type / Control: MMxxx
Year of construction: 2016
Machine No.: 0815 4711

satisfies the essential requirements of the European regulations
European Machine Directive 2006/42/EC
EMC Directive 2014/30/EU

and the harmonized standards
EN 60204-1:2006/ A1: 2009/ AC: 2010 Electrical equipment of machines-
Part 1: General requirements
EN 13128:2001 / A2: 2009/ AC: 2010 Safety of machine tools - Milling
machines
EN ISO 12100: 2010 Safety of machinery - General principles for design -
Risk assessment and risk reduction

Furthermore, we confirm that the technical file s for this machine have
been carried out according to enclosure VII, part A. If requested, we
undertake to transfer the documents to the Market Surveillance Authority.

The undersigned of the conformity declaration is authorized to complete the
relevant technical documents.

We hereby confirm the correctness of the above-mentioned indications.

Anytown,

.....
John Doe
(Managing Director)

Above: Example of Declaration of Conformity for milling machine
Source: VDW, Germany

CE marking & warning signs

Is the official CE marking used?

The CE marking consists only of the letters 'CE' with the graphic form shown in the diagram of the Directives and in the Regulation 765/2008.

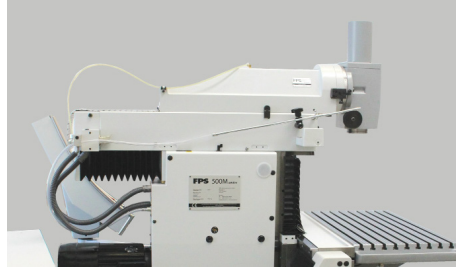
The various components of the CE marking must have the same vertical dimension, which may not be less than 5 mm. The minimum dimension may be waived for small-scale machinery.

The CE marking must be affixed to the machinery visibly, legibly and indelibly in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique.



Where can the CE marking be placed?

The CE mark has to be in an obvious place and it has not to be confused with CE marking of components. With regards to the size of the machinery, marking should be easily readable. Marking should not be effaced during the lifetime of machinery under its expected conditions of use. If the marking is displayed on a plate, it should be permanently fixed to the machinery, preferably by welding, riveting or bonding.



Above: Example of placing CE marking on the machine
Source: FPS

Which components might need CE marking?

The Machinery Directive applies to completed machines and assemblies and not to components, except safety components and lifting accessories. Safety components and lifting accessories must apply all obligations specified in the Machinery Directive as they are considered as 'machinery' in the broad sense and must meet all essential health and safety requirements of the Directive.

However, there are some components that might need CE marking according to other Directives.

In such cases manufacturers of the components are obliged to comply with the formalities of the relevant Directive(s) and mark the products accordingly. The manufacturer of the machine will indicate in the instructions which marks have been affixed pursuant to other Directives and any obligations they may involve (such as compulsory periodical testing, inspection or replacement).

Items of pressure equipment or pressure assemblies should bear CE marking in case they fall under the provisions of article 4 of the PED Directive (2014/68/EU)⁴. Otherwise, they should only bear marking to permit identification of the manufacturer or the authorized representative⁵.

Who can affix the CE marking?

It is the responsibility of the manufacturer or his authorised representative to affix the CE marking.

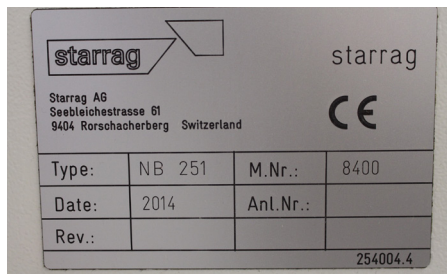
An authorised representative is the natural or legal person mandated by the manufacturer in writing. The written mandate entitles the representatives to perform all formalities and obligations on behalf of the manufacturer for the machine in question.

What shall be included on the nameplate?

- Business name and full address of the manufacturer and, where applicable, the authorised representative
- Designation of the machinery
- CE Marking
- Designation of series or type
- Serial number and/or batch number
- The year of construction, that is the year in which the manufacturing process is completed
- This data shall be in one official EU language. More data can be included, but these are the minimum requirements by the Machinery Directive⁶.

In which language shall the instructions be?

The machinery must be accompanied by instructions in the language of the country



Above: Example of a name plate
Source: Starrag AG, Switzerland

where the machine is intended to be used. If this language deviates from the language of the original instructions the machinery must be also accompanied by the original instructions in one of the official EU languages (Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish).

In which language should the technical file be?

This data does not need to accompany the machinery. The manufacturer must have it ready and it must be at least in one of the official EU languages.

What shall the machine not bear?

The machine shall not bear any misleading signs similar to CE marking, even if these are additional to the original CE marking. Neither shall the CE marking be covered by other signs.

What about the obligations for the importer/distributor?

It is the responsibility of the importer and distributor to make sure that only products complying with legislation and bearing the

⁴ Pressure Equipment Directive (2014/68/EU), Art. 4.3.

⁵ Pressure Equipment Directive (2014/68/EU), Art. 18.

⁶ Machinery Directive 2006/42/E, Annex I 1.7.3.

CE marking are placed on the market. In cases where a milling machine is produced in third countries and the manufacturer is not represented in the European Economic Area (EEA), the importer must make sure that the machine placed on the market by them complies with the EU requirements and does not present a risk to health and safety. The importer must verify that the manufacturer from outside the EU implemented the necessary steps to ensure compliance and that the documentation is available upon request and that a person is named which is authorised to compile the technical file and which is represented in the EEA.

Are the CE marked milling machines tested and approved by the authorities?

The assessment that milling machines conform to the legislative requirements applying to them is the sole responsibility of the manufacturer or his authorized representative. Thus it is the manufacturer himself who affixes the CE marking. It is also the manufacturer who drafts the EC Declaration of Conformity.

Which warnings should be included on milling machines?

The manufacturer is not expected to mark on the machinery all of the information for safe use provided in the instructions. However, information concerning essential aspects of safe use must be marked on the machinery. The information to be marked on the machinery is usually specified in the relevant harmonised standards and has to be in the language of the member state in which the machinery is placed on the market and/or put into service. It may be accompanied, on request, by versions in any other official Community language or languages understood by the operators. Possible warnings on a milling machine:

- Maximum dimensions of workpieces.

- Maximum dimensions of the tools to be used.
- Other warning signs.

Examples of possible safety sign affixed to the machine



Verifying the conformity of the machine

There is a list of safety requirements that may be checked by visual inspection of the milling machine. This list provides a number of questions that need to be answered in order to check the conformity of a milling machine. However, this list does not claim to be exhaustive and it does not include specific requirements for certain types of milling machines, which can be found in

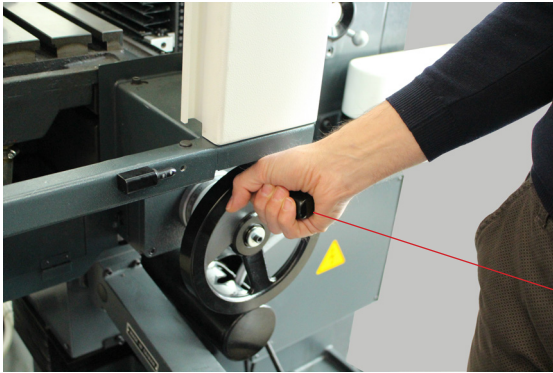
the respective Directives and harmonized standards.

Therefore, conformity with the checklist does not demonstrate full compliance with the Machinery Directive 2006/42/EC. It rather indicates whether health and safety requirements have or have not been met.

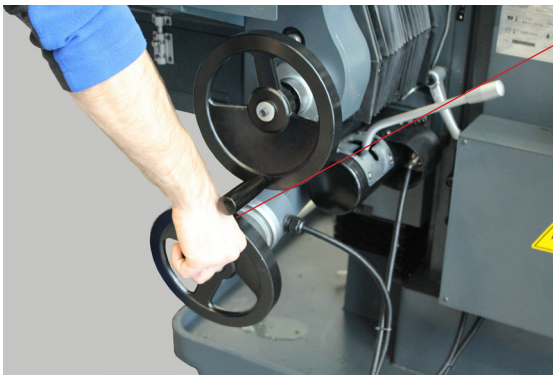
Basic checklist for visual inspection

Safety requirement and/or protective measure	Yes/No
CE marking shall be affixed to the machine in a clearly visible and permanent manner.	
Information including business name and full address of the manufacturer; designation of the machinery; serial number and/or batch number and the year of construction shall be declared on the machine.	
The machine should be equipped with emergency stop control device.	
To avoid crushing hazard by using handwheels the machine can be equipped with safety manual handwheels.	
Wrench must eject automatically (for example by spring tension).	
Following zones require safeguarding during machining operations of automatic machines: working area, tool magazine, tool changing magazine, swarf/chip collection and removal, workpiece transfer devices. The used guards can be fixed and/or interlocked guards (with or without guard locking). If needed, other guards can be provided (protected operator position like cabin, fencing; laser scanners or others).	

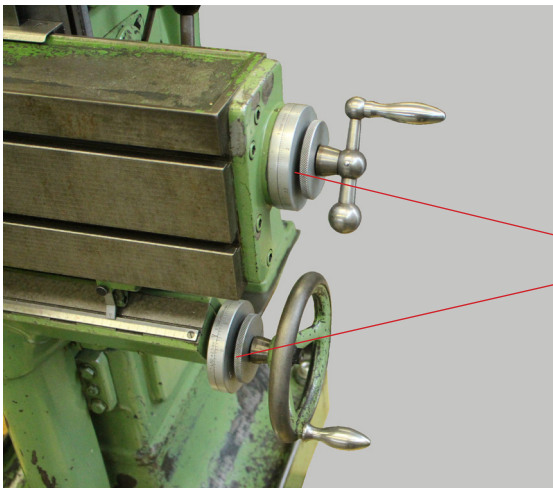
Safety requirement and/or protective measure	Yes/No
To avoid ejection of parts (e.g. swarf, chips, parts of tools) as well as ejection of metalworking fluid the machine needs to be equipped with appropriately designed guards. The guards should be in compliance with type C-standards, e.g. EN 12417, EN 13128.	
Access to hazardous power transmission parts such as belts, chains, gears, pulleys, shafts, etc. should be protected by fixed or interlocked guards (with or without guard locking).	
The guarding of the working zone should be designed according to type C-standards, e.g. EN 12417, EN 13128.	
In case routine observations are required the machine should be equipped with means (e.g. windows) to avoid opening, removing or suspending any work zone guard and/or other protective device according type C-standards, e.g. EN 12417, EN 13128.	
The machine should be equipped with a supply disconnecting (isolating) device see EN 60204-1 5.3. This is to avoid occurrence of accident due to electrical shock or burn or malfunction.	
The system should be designed in a way which prevents occurrence of splash, leakage and overflow of the metalworking fluid.	
To minimize the occurrence of accidents, resulting from slips, trips and falls, the machine should be designed in a way which makes places of work and access to the machine safe. Additionally, warnings about hazards and precautions should be included in the instruction handbook.	
Each machine shall be accompanied by an instruction handbook. The instructions of use shall contain information about noise emission according to the Machinery Directive.	
Milling machines must be capable of being handled and transported safely.	



Crushing hazard
by using
the handwheels.



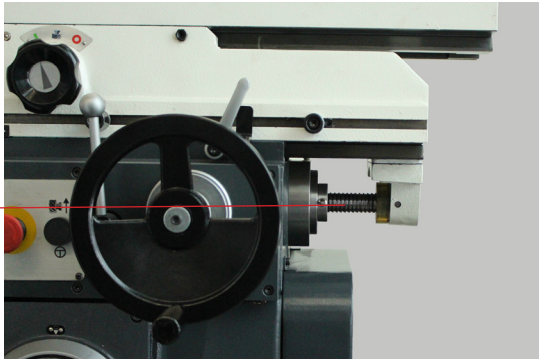
Above: Examples of non-compliance: crushing hazard by using the handwheels. Source: FPS, Germany



Safety handwheels
must be mounted.

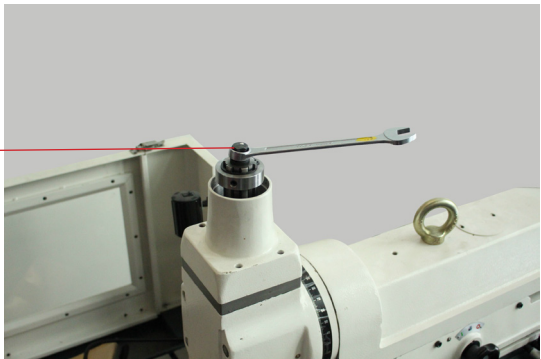
On the left: Example of non-compliance: lack of safety handwheels. Source: FPS, Germany

Crushing hazards
by movable axis.



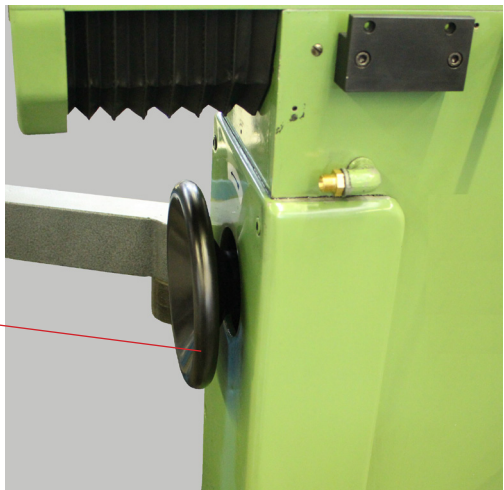
Above: Example of non-compliance: crushing hazards by movable axis. Source: FPS, Germany.

Wrench must
eject automatically
(for example
by spring tension).



Above: Example of non-compliance: wrench not ejected automatically. Source: FPS, Germany.

No access
to rotating parts.



Above: Example of non-compliance: no access to rotating parts. Source: FPS, Germany.

Definition of a milling machine

As defined by ISO/FDIS 16090-1, a milling machine is a machine designed to shape cold metal by the use of a rotating cutting tool. We divide the milling machines into manual and automatic machines. Manual milling machines have controlled axis motion through the actuation of a hand wheel. In case that the machine is single powered the axis are controlled by mechanical, electrical or other means. We talk about automatic milling machines where the axis are moved in a programmed way.

ISO/FDIS 16090-1 (see 3.2.3 and 3.1.1/3.1.5./3.1.6) defines a machining centre as a numerically controlled machine tool, where the spindle orientation is usually either horizontal or vertical, capable of carrying out two or more machining processes (e.g. milling, drilling, boring) and having facilities to enable tools to be changed automatically from a magazine or similar storage unit in accordance with the machining program. Such machines may incorporate facilities for manual control in varying degrees.



Above: Milling machine.
Source: FPS, Germany.



Above: Milling machine.
Source: FPS, Germany.

Moveable guards

EN13128, EN12417, and ISO/FDIS16090-1 are dealing with fixed and moveable guards of milling machines. These are all important for protection against unintended access to the working zone, in which the milling tool is rotating and the milling

workpiece is alternating, both causing risks of entanglement, crushing and shearing. Therefore, this CE guide contains the illustrations out of the EN 13128 or ISO/ FDIS 16090-1, which indicate how these risks can be coped with.

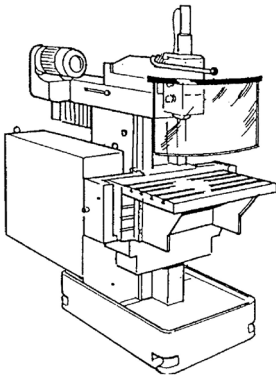


Fig. X.1: Partial enclosure (with or without interlocking)

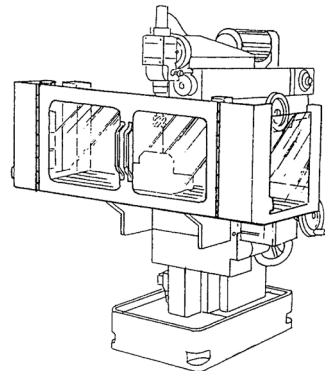


Fig X.2: Full enclosure (with interlocking)

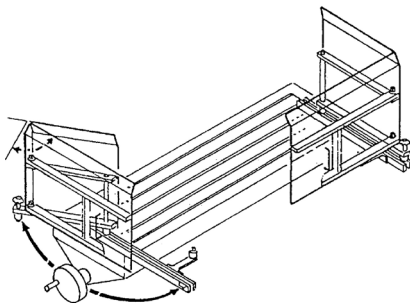


Fig. X.3: Partial enclosure (without interlocking)

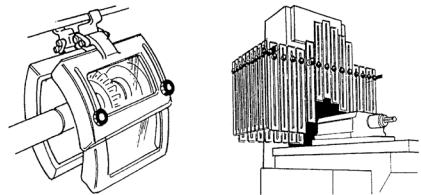


Fig. X.4: Partial enclosure (with or without interlocking)

Accompanying instructions

All machinery shall be accompanied by (a booklet of) instructions of use in the official Community language or languages of the Member State in which it is placed on the market and/ or put into service. The instructions of use shall be made according to the Annex I, Section 1.7.4 of the Machinery Directive.

It shall contain the basic elements of the EC declaration of conformity along with other details (the following is not an exhaustive list):

- Business name and full address of the manufacturer and of his authorised representative.
- A general description of the machinery and the designation of the machinery as marked on the machinery itself, except for the serial number.
- Drawings, diagrams, descriptions and explanations necessary for the assembly, use, maintenance and repair of the machinery and for checking its correct functioning.

- Warnings concerning ways in which the machinery must not be used that experience has shown might occur.
- Recommendations that the operator does not carry out actions which could reduce the protection offered by the safeguards (like the removal of a safety component)
- At least all the warnings that are placed on the machinery.
- A declaration on airborne noise emission. The declaration shall include verification of noise emission values.

By way of exception, the maintenance instructions intended for use by specialized personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand⁷.

⁷ Machinery Directive 2006/42/EC, Annex I, 1.7.4

Transportation information

Milling machines must be capable of being handled and transported safely and must be packaged or designed so that they can be stored safely and without damage.

Machinery and its components and fittings must be stable enough to avoid overturning, falling or uncontrolled movements during transportation/ assembly/ dismantling and any other possible movements. The machine tool must be packaged for transport to the user's premises and designed and constructed so that it can be safely loaded, transported, unloaded and moved to the place of installation.

As the weight and size of milling machine tools prevent them from being portable by hand, such machinery or each component part (not portable by hand and transported

separately and not being incorporated into the machinery) must be:

- fitted with attachments for a lifting gear; or
- designed so that it can be fitted with such attachments; or
- be shaped in such a way that standard lifting gear can easily be attached.

Examples of lifting gears include gears with crane blocks, wire rope blocks, sheaves, swivels, sockets, turnbuckles and hooks.

Each machine shall be marked in a distinct and permanent manner with lifting points for transportation and installation purposes where applicable.

Safety signs on transportation related information are not obligatory to be put on the machine, but could be recommended.

Examples of machine lifting



Source: FPS, Germany.

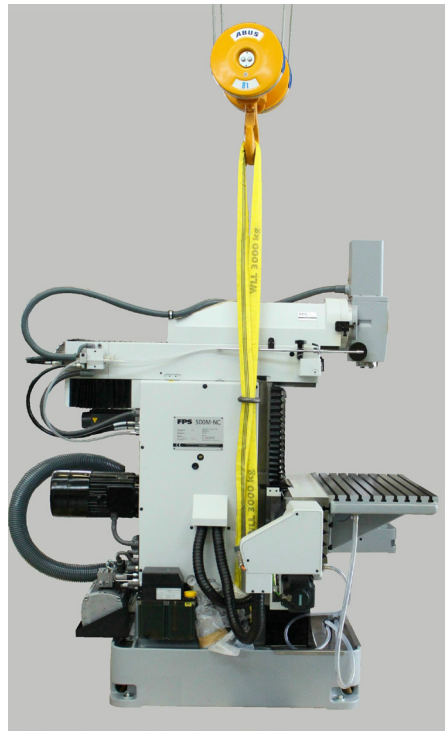


Source: FPS, Germany.

Examples of machine lifting



Source: FPS, Germany.



Source: FPS, Germany.

Notes:

The document provides the reader with general guidance for good practice and should only be taken as suggestions or observations for consideration when addressing issues relating to CE marking on metalworking milling machines.

This document is also available on the CECIMO website:
<http://www.cecimo.eu/site/publications/ce-guides/>

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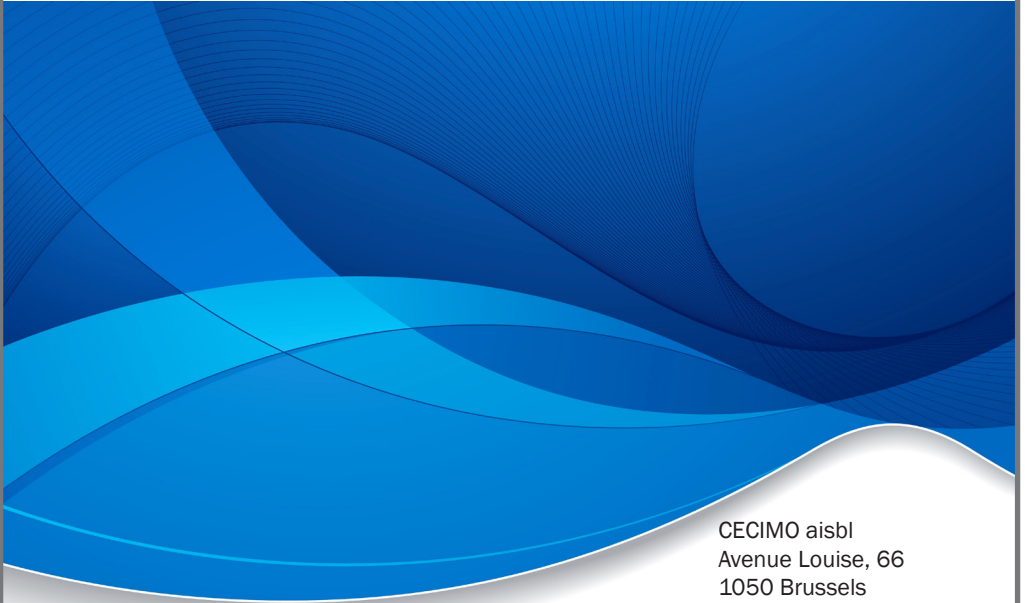
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CECIMO is the European Association representing the common interests of the European Machine Tool Industries. We bring together 15 National Associations representing over 1300 industrial enterprises in Europe, over 80% of which are SMEs. Innovation and R&D are high on our agenda to promote the development of the industry in the fields of economy, technology and science.

A large abstract graphic consisting of overlapping, flowing blue waves in various shades of blue, creating a sense of movement and depth. It occupies the lower half of the page.

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