Clamping devices for use on machines

This position paper is intended as information on how clamping devices are to be regarded within the context of Machinery Directive 2006/42/EC or other statutory regulations. This position paper concentrates on clamping devices that are activated manually or operated by means of external energy, such as electric, hydraulic, pneumatic, magnetic energy or by spring forces. In particular, devices for the purpose of fixing in place workpieces, tools or assemblies are regarded as clamping devices.

Note:
Tools of forming machines and punching tools are not covered here.

In practice, the question is frequently raised of what legislation applies to clamping devices that are intended to be used on machines.

The products that are covered by the range of applications specified by Article 1 Paragraph 1 of Machinery Directive 2006/42/EC are defined in Article 2:

a) machines;
b) interchangeable equipment;
c) safety components;
d) load-handling attachments;
e) chains, ropes and straps;
f) removable cardan shafts;
g) partly complete machines.

The features of Article 2 d, e and f do not apply for clamping devices.

The sections below examine whether clamping devices exhibit the features of Articles 2 a, b, c or g.

Note:
This position paper serves only as a starting point, and merely provides an overview for the classification of clamping devices under the relevant statutory regulations and for how to apply Machinery Directive D2006/42/EC. It makes no claim to completeness, nor to providing a final interpretation of current legislation. Furthermore, it is not intended to replace a study of the relevant guidelines, laws and ordinances. In addition, the idiosyncrasies of the products involved must be taken into due account, as well as their different application options. As a consequence, a variety of further interpretations are conceivable.
Clamping devices are not machines, since they do not have a particular application, as laid down under Article 2(a) of the Machinery Directive. Further explanations on the salient feature of the particular application involved can be found in § 35 of the official guideline for the Machinery Directive.

Clamping devices are not normally interchangeable pieces of equipment
Interchangeable pieces of equipment are defined as follows in Article 2(b) of Machinery Directive 2006/42/EC:
“a device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool.”

The function of a clamping device is to clamp and fix in place tools or workpieces. This means it does not alter or extend the function of the machine concerned. Rather, the clamping device is necessary for the intended use of a machine.

A clamping device is not a tool either. A workpiece is machined by a tool.

The machine is always started up with a clamping device fitted. Clamping devices are also replaced by the operator even after a machine has been put into operation; however, this is not for the purpose of altering or extending the functionality of the machine concerned. When a clamping device is replaced, the aim is to clamp and fix in place tools or workpieces with different geometries.

The manufacturer defines the intended use of the machine within the context of the conformity assessment procedure in the operating manual for the machine, and the specification for using suitable clamping devices. Every clamping device that conforms to the technical specification of the machine’s manufacturer is accordingly covered by the machine’s protection concept.

Clamping devices that are classified as interchangeable pieces of equipment within the meaning of Article 2(b) of the Machinery Directive have to comply with all features of this definition, and accordingly have to change or extend the intended purpose of the machine on which they are mounted.

Clamping devices are not safety components
Safety components are defined as follows in Article 2(c) of Machinery Directive 2006/42/EC:
“... a component:
— which serves to fulfil a safety function,
— which is independently placed on the market,
— the failure and/or malfunction of which endangers the safety of persons, and
— which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.”

All four of the criteria listed above must be met for a component to be classified as a safety component.

Safety components are defined as components that are not required for the actual operation of a machine. In this context, see § 42 Paragraph 2 – Guideline to Machinery Directive 2006/42/EC:
“... However, purely operational components are not considered as safety components. ... “
A clamping device is required in order to use a machine for its intended purpose.

**Clamping devices are not partly completed machines**

Partly completed machines are defined as follows in Article 2(g) of Machinery Directive 2006/42/EC:

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

The definition shows that only those products are regarded as partly completed machines that are intended for installation “into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies”.

A clamping device is in terms of its complexity not a “totality that almost constitutes a machine”. Clamping devices lack certain constituents that are necessary for being able to perform a particular function (see Guideline to the Machinery Directive 2006/42/EC § 46 Paragraph 3).

§ 46 Paragraph 2 – Guideline to Machinery Directive 2006/42/EC:

“Partly completed machinery subject to the Machinery Directive is a product intended to form machinery that is in the scope of the Machinery Directive after incorporation.”

Since clamping devices are not only put into circulation by the machine’s manufacturer in conjunction with the machine itself, but can/must also be procured and/or replaced by the operator of the machine himself, a clamping device in accordance with § 46 Paragraph 2 – Guideline to Machinery Directive 2006/42/EC – cannot be defined as a partly completed machine.

**Statutory requirements for clamping devices**

When clamping devices used on machines are not machines, are not partly completed machines, not safety components, and not interchangeable pieces of equipment within the meaning of Machinery Directive 2006/42/EC, it might be thought that such clamping devices do not have to conform to any health and safety requirements whatever. This, however, is not the case.

For products that are not covered by the European harmonisation regulations, the individual statutory regulations of the member states must be applied, which nonetheless entail a requirement for safe products, which in the mechanical engineering sector are expected to conform to the current state of the art. In Germany, the German Product Safety Act (ProdSG) must be applied in this regard. These statutory regulations obligate the manufacturer to put solely safe products into circulation. For clamping devices, this means, for example, that no hazards may be caused by clamping devices during operation, make-ready, maintenance, transport or storage.

**Tasks and duties of the manufacturer of clamping devices**

The manufacturer of clamping devices must always take care to ensure protective measures that conform to the current state of the art and where appropriate affix warnings to the clamping device, and in the operating manual warn against residual risks if no further
technical measures are available for risk mitigation. When clamping devices are integrated into the machines concerned, these residual risks must always be taken into due account.

In order to achieve a level of safety that conforms to the current state of the art and thus also to the German Product Safety Act (ProdSG), all existing risks and risk mitigation measures must be documented in the manufacturer’s own risk assessment, and all further technical documents required must be drawn up, such as the operating manual, calculations, etc.; in this context, see the appendix to this document.

For performing the risk assessment and drawing up the technical documentation, EN ISO 12100 can be adduced. For determining the state of the art and determining the interface\(^1\) to the machine, the relevant Type-C standards for the machine (e.g. EN 12417, EN 13218, EN 14070, FDIS/ISO 16090, ISO 23125) and where appropriate the further standards relevant for the clamping device (e.g. ISO 4413, ISO 4414, EN 1550/ISO16156, ISO13849-2) will be found helpful.

**Marketing non-harmonised products in Europe**

ORDINANCE (EC) No. 764/2008\(^2\) addresses the prohibition on measures taken by national government agencies designed to prevent the marketing of products in states of the European Economic Area that have already been lawfully marketed in a member state of the European Union.

Since no harmonised specifications exist for clamping devices, clamping devices that conform to the stipulations laid down in this position paper can also be marketed unhindered in other EU states.

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\(^1\) The term “interface” subsumes, for example, the mechanical, hydraulic, pneumatic, electrical coupling of the sensors and actuators between machine and clamping devices. Plus the mechanical mounting for the intended use in the machine.

\(^2\) ORDINANCE (EC) No. 764/2008 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL dated 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC
Individual aspects regarding the use of clamping devices

Machine manufacturer supplies a machine together with a clamping device
If the clamping device has already been integrated into the machine by the manufacturer, then the manufacturer of the machine shall take this into due account in the conformity assessment procedure for the machine concerned. The machine manufacturer shall here ensure that the clamping device is suitable for its intended purpose.

Taking due account of the relevant directives and standards (see “Tasks and duties of the manufacturer of clamping devices”), he shall perform a risk assessment procedure for all phases of the device’s lifetime, and shall derive therefrom the requisite technical protective measures, plus the necessary warnings for inclusion in the operating manual, and the warning signs affixed to the machine and the clamping device. All protective measures will here relate solely to the clamping device(s) defined by the machine’s manufacturer. For example, besides the design for the intended purpose, the safety functions are also defined specifically in relation to the integrated clamping devices.

Machine manufacturer supplies clamping devices that can be used on several different machines as desired
When the manufacturer of a machine supplies one clamping device or several clamping devices, and this/these can be used for their intended purpose or mounted/replaced by the operator in one or more machines from the manufacturer concerned, then the manufacturer of the machine(s) must comply with the health and safety requirements as laid down in Appendix I of the Machinery Directive and perform a risk assessment procedure for all phases of the lifetime. He shall derive therefrom the requisite technical protective measures, plus the warnings for inclusion in the operating manual(s), and the warning signs affixed to the machine(s) and the clamping device(s). All protective measures will here relate solely to the clamping device(s) defined by the machine’s manufacturer.

For example, besides the design for the intended purpose, the safety functions are also defined specifically in relation to the integrated clamping devices.
This is done taking into due account the relevant directives and standards (see “Tasks and duties of the manufacturer of clamping devices”).

Machine manufacturer supplies a machine without a clamping device
If a machine is supplied without a clamping device, the clamping device to be procured by the operator will not have been covered by the conformity assessment procedure of the machine’s manufacturer.
In such cases, the conformity assessment procedure will cover only the machine itself, including the interfaces for the clamping device, but without a clamping device.
The operator has two options here:
• he purchases or procures the clamping device from a manufacturer of clamping devices
• he himself produces the clamping device

Operator purchases or procures clamping devices
In many cases, the operators of a machine purchase the clamping device(s) to be integrated into this machine not from the machine’s manufacturer, but directly from a manufacturer of series or special devices. Then the operator of the machine has to perform a hazard assessment regarding the minimum regulations for health and safety when the equipment is being used by employees in accordance with the Use of Work Equipment Directive 2009/104/EC and evidence that the health and safety requirements are being met. For the manufacturer of the clamping device(s), the requirements laid down under “Tasks and duties of the manufacturer of clamping devices” shall apply. The manufacturer of the clamping
device shall in the operating manual provide the requisite information for installing the clamping device in the machine and for safe operation of the clamping device with the machine.

The responsibility for ensuring that the clamping devices have been properly affixed or installed, and that they are suitable for the prepared interface and for the machine’s intended purpose, shall in this case be borne solely by the operator.

**The operator himself is the manufacturer of the clamping devices**

If the operator is the manufacturer of a clamping device, he shall bear the responsibility for ensuring that the clamping devices meet all safety requirements and the statutory duties involved.

The operator must accordingly meet all requirements entailed for operation of the machine by labour legislation, plus the relevant requirements as a manufacturer. In order to achieve this, the above-specified “Tasks and duties of the manufacturer of clamping devices” must be complied with.

**Replacing a clamping device**

When replacing a clamping device, care must be taken to check whether what is involved is a modification or even a major change to the machine. In this context, the interpretation paper of the BMAS\(^3\) provides important tips and aids to decision-making:

“A product that after being put into operation has undergone major changes or revisions with the aim of modifying its original performance, use or construction entailing significant effects on compliance with the statutory harmonisation regulations of the Union can be regarded as a new product. This must be decided from case to case, and in particular against the background of the aims of the statutory regulations and the type of products involved within the range of application of the statutory regulation concerned.”

The replacement of a clamping device in a machine does not normally constitute a major modification, since it does not lead to new hazards or new risks for the machine. In this case, the machine does not create a new hazard that generates an additional risk or exacerbates an existing one. The clamping device is installed at the mounting points specified for the machine and connected to the power supply interfaces likewise specified for the machine.

The responsibility for ensuring that the clamping devices have been properly affixed or installed, and that they are suitable for the prepared interface and for the machine’s intended purpose, shall in this case be borne solely by the operator.

\(^3\) Interpretation paper on the subject "Major Changes to Machines"
Appendix: Proposal for a procedure designed to meet the requirements arising from the German Product Safety Act

1. Performing a risk assessment procedure modelled on EN ISO 12100

   The risk assessment forms part of the technical documentation. This shall be kept on the manufacturer’s premises and can be submitted to government agencies as evidence of compliance with the statutory requirements involved.

2. Drawing up an operating manual

   An operating manual must be drawn up for each clamping device within the meaning of the German Product Safety Act (ProdSG).

   Note:
   Contents modelled on Machinery Directive, Appendix I No. 1.7.4.2

   Language version:
   Individual states’ stipulations must be complied with. Both the European and the individual countries’ regulations on product safety contain a provision requiring the operating manual to be supplied in a language that is an official language of the country in which the clamping device is put into circulation or put into operation.

3. Drawing up installation instructions for fitting the clamping device on the machine

   Note:
   Contents modelled on the Machinery Directive, Appendix VI

   Language version:
   The language version of the installation instructions can be agreed between the contracting parties, with preference being given to an official language of the European Community. If no agreement exists, the installation instructions should be supplied in a language that is an official language of the country in which the clamping device is put into circulation or put into operation.

4. Identification of the clamping device

   Identification modelled on EN1550 Section 6.3.1 or ISO 16156 Section 6.3.

5. Issuance of a certificate (sample)

   Manufacturer:
   (Company’s name)
   (Address)

   Product:
   (Designation)
   (Type)
   (Serial Number)

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The manufacturer certifies that for the above-mentioned product:

- a risk assessment procedure modelled on EN ISO 12100 has been performed
- where relevant it complies with national and European standards, e.g. EN1550
- an operating manual has been drawn up whose contents are modelled on the
  Machinery Directive, Appendix I No. 1.7.4.2
- installation instructions have been drawn up whose contents are modelled on the
  Machinery Directive, Appendix VI
- identifiers have been provided that are modelled on EN1550 Section 6.3.1 or ISO
  16156 Section 6.3.