MACHINERY DIRECTIVE
2006/42/EC

Information on Implementation and Application
HYDAC Information

Product requirements

- Laws
- Regulations
- Directives
- Regulatory framework
- Standards
- Specifications

Hydraulic Components
Subsystems and Systems

- New Machinery Directive 2006/42/EC

Editorial information

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1. Legal foundations
Legal requirements of products

1.1 Equipment and Product Safety Act (GPSG)
Under the Equipment and Product Safety Act (GSPG), the European directives which contain requirements of certain product groups (e.g. also for technical equipment) are implemented nationally (in Germany) in the form of regulations.

For the HYDAC Group in particular, the following laws must be complied with:
1st GPSGV Electrical equipment Low voltage directive 2006/95/EC
6th GPSGV Simple pressure vessels SPV Directive 2009/105/EC
9th GPSGV Machinery Machinery Directive 2006/42/EC
11th GPSGV Equipt. for potentially ex. areas ATEX Directive 94/9/EC
14th GPSGV Pressure equipment PED Directive 97/23/EC

In addition to the GPSG, there are other parallel statutory regulations such as the laws on EMC, Construction Products or Medicinal Products which can apply.

The standards applicable to the directives enacted according to EC Treaty Article 95 (internal market) are listed by the EU Commission in the Official Journal. These are harmonised standards (valid throughout the EU). Particularly when applying what are known as Type C standards, a presumption of conformity is implied.
The harmonised standards (see Fig. 3) compiled by the European Committee for Standardization CEN (Comité Européen de Normalisation) on behalf of the EU Commission under the Machinery Directive – selected examples are also listed below the particular types - are subdivided as follows (see Fig. 2)

Type A standards  
Safety basis standards

- General principles for design
  - [DIN] EN ISO 12100 Part 1 and 2 (formerly EN 292 Part 1 and 2)
  - [DIN] EN ISO 14121 Part 1 (formerly EN 1050)

Type B standards  
Specific safety standards (Generic safety standards)

Type B1  
Particular general overriding safety aspects
- [DIN] EN ISO 13489 Part 1 Safety-related parts of control systems
- [DIN] EN IEC 60204 Electrical equipment of machines

Type B2  
Specification of particular safeguards
- [DIN] EN 574 Two-hand control devices
- [DIN] EN ISO 13850 (formerly EN 418) Emergency stop – Principles for design

Type C standards  
Machinery safety standards

- Specific safety requirements of individual machinery
  - [DIN] EN 12417 Machine tools – Safety – Machining centres

Fig. 2: Hierarchy of standards - harmonised standards relating to the Machinery Directive
NOTICES FROM EUROPEAN UNION INSTITUTIONS AND BODIES

COMMISSION


(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the Directive)

(2009/C 214/01)

<table>
<thead>
<tr>
<th>European Standards Organisation (1)</th>
<th>Reference and title of the harmonised standard (and reference document)</th>
<th>First publication OJ</th>
<th>Reference of superseded standard</th>
<th>Date of cessation of presumption of conformity of superseded standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEN</td>
<td>EN 81-3:2000+A1:2008 Safety rules for the construction and installation of lifts — Part 3: Electric and hydraulic service lifts</td>
<td>This is the first publication</td>
<td></td>
<td></td>
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<td>CEN</td>
<td>EN 81-40:2008 Safety rules for the construction and installation of lifts — Special lifts for the transport of persons and goods — Part 40: Stairlifts and inclined lifting platforms intended for persons with impaired mobility</td>
<td>This is the first publication</td>
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<tr>
<td>CEN</td>
<td>EN 115-1:2008 Safety of escalators and moving walks — Part 1: Construction and installation</td>
<td>This is the first publication</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig. 3: List of harmonised standards – Official Journal of the EU
The new Machinery Directive 2006/42/EC replaces the previous Machinery Directive 98/37/EC with effect from 29.12.2009 without a transitional period (Fig. 4). Much of the content, particularly for machinery, remains unchanged (Fig. 5).

Fig. 4: Legislative procedure for the new Machinery Directive

Fig. 5. Structure of the new Machinery Directive 2006/42/EC
1.2 Machinery Directive (implementation into German law 9th GPSGV)

The scope of the new Machinery Directive includes, amongst others, the following groups which are also defined in the Definition of Terms (Art. 2):

Machinery:
An assembly consisting of linked parts, at least one of which moves (and also machine systems, i.e. assemblies of machinery, which are arranged and controlled so that they function as an integral whole).

Partly completed machinery (formerly part-machines):
…cannot in itself perform a specific function, and will only be complete once incorporated into a complete machine including all necessary protective means.

Safety components (Art. 2, c and Ann. V – non-exhaustive list):
Components which fulfil a safety function e.g. light barriers, safety mats, automatic mobile protective devices.

Interchangeable equipment:
changes the function of machinery, e.g. accessories or attachments (swivel, turning, tipping devices) for a basic machine.

etc.

Some exceptions are listed in Article 3 of the new Machinery Directive. Further limits are set in this case ("Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives.").

In the HYDAC Group, the Machinery Directive is implemented by product group in the individual Departments or Product Divisions. In particular there are changes in the scope of the directive.

The scope of the directive has been more precisely defined. For example, lifting accessories are included in the scope (Art. 1). The borderline between the scopes of other directives, e.g. the Low Voltage Directive 2006/95/EC, has been better defined. In respect of partly completed machinery (formerly part-machines) there are new regulations regarding the scope of documentation (now a risk assessment must also be carried out) and the submission of a written declaration. The previous manufacturer’s declaration has been replaced by a Declaration of Incorporation in accordance with Annex II B. Installation instructions shall accompany partly completed machinery. A person authorised to compile the documentation shall ensure the necessary technical documentation is presented to the authorities for inspection, on request, within a reasonable period of time (interpretation depends on the complexity: five to ten working days).

HYDAC has assessed its product categories and product classes (Fig. 8) in respect of the new Machinery Directive on the basis of the VDMA position paper (Fig. 6) dated 29.07.2009 (Version 1 dated 28.01.2009) and the CETOP position paper dated 26.06.2009. In addition, the development of the "Guide to application of the Machinery Directive 2006/42/EC" of the EU Commission (Fig. 7) has been followed carefully. Amongst other things, valves and hydraulic cylinders are, for example, excluded from Art. 2 of the Machinery Directive because they are components.
Fig. 6: VDMA Position Paper on Fluid Power dated 29th July 2009

Fig. 7: Guide to the Application of the new Machinery Directive
2. Categorisation (What is machinery?)

Machinery Directive 2006/42/EC

<table>
<thead>
<tr>
<th>Old</th>
<th>New</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assembly / Components</td>
<td>Partly completed machinery</td>
</tr>
</tbody>
</table>

Also supplied by HYDAC

- Declaration of conformity
- CE marking
- Operating instructions

- Declaration of incorporation
- Installation instructions
- Delivery note with relevant text blocks

Fig. 8: Simple overview of HYDAC Group products

a) Machinery;
b) Interchangeable equipment;
c) Safety components;
d) Lifting accessories;
e) Chains, ropes and webbing;
f) Removable mechanical transmission devices;
g) Partly completed machinery;

Fig. 9: Scope of Directive 2006/42/EC for comparison
2.1 Categorisation of the HYDAC product range

As a manufacturer, HYDAC has a wide range of products (see Table 1), and supplies products ranging from components to machinery. Generally speaking, components are not specified in directives in more detail and form the largest proportion of the product range.

For machinery and safety components a Declaration of Conformity shall continue to be issued and Operating Instructions shall continue to accompany the products. The original operating instructions are generally issued in German. Other versions are simply a translation of the original documents. If the HYDAC machinery is placed directly on the market in another country of the EU, then the customer will receive a translation of the original in the official language of the user country. In principle there is almost no change to the previous procedure. The machinery is labelled with the CE-mark at the end of what is known as the conformity assessment procedure.

In the case of partly completed machinery, it is now clear that there are extensive responsibilities. These responsibilities include an appropriate procedure for the conformity assessment. The essential health and safety at work requirements from Annexe I must be selected. In order to do this, the input for a risk assessment (in accordance with EN ISO 14121) shall be provided. The residual risks shall be communicated. Within the framework of drawing up the documentation (relevant technical documentation) a Declaration of Incorporation shall be issued in an official language. The customer receives installation instructions in an official language. The languages German, English and French are provided as standard. Other languages can be agreed contractually. The Machinery Directive does not stipulate that these instructions be made available in the language of the user country. Partly completed machinery shall not bear the CE mark.
<table>
<thead>
<tr>
<th>Scope of application</th>
<th>Old Machinery Directive</th>
<th>New Machinery Directive</th>
<th>HYDAC Applications</th>
</tr>
</thead>
</table>
| "Complete" machinery | – Declaration of conformity  
– CE marking  
– Operating manual | – Declaration of conformity  
– CE marking  
– Operating instructions | – Fluid service equipment  
– Test rigs  
– Nitrogen charging units  
– Actuators (with mounting) |
| Partly completed machinery | – Manufacturer's declaration | – Declaration of incorporation  
– Installation instructions | – Hydraulic power units  
– Oil lubrication systems  
– Tank packs  
– Sub-assembly with control system (with mounting) |
| Safety components | Not included or only limited inclusion (affected, however, on the basis of the guidelines or included in the guidelines.) | – Declaration of conformity  
– CE marking  
– Operating instructions | – 2-out-of-3 safety valve is relevant for HYDAC as long as no specific directive applies.  
– e.g. for pressure relief valve according to Pressure Equipment Directive |
| Parts / Components | Are not covered by the Machinery Directive (but: Equipment and Product Safety Act must be taken into account) | Are not covered by the Machinery Directive (but: Equipment and Product Safety Act must be taken into account) | Approximately 90 % of the HYDAC portfolio. |

Table 1: Scope of application of the Machinery Directive - Categorisation with focus on HYDAC products
Components (and assemblies) such as filters, filter elements, hydraulic accumulators, pumps, valves, cylinders etc are normally excluded from the scope of the Machinery Directive. There are, however, standards e.g. EN 982, covering the safety requirements for hydraulic systems. If no other directive applies as a legal basis, they are subject to the (German) Equipment and Product Safety act. On the delivery note we advise that the products supplied by us are intended to be incorporated into other systems (plant, vehicles or similar).

2.2 Conformity assessment

The technical file (Ann. VII A) for machinery or the relevant technical documentation (Ann. VII B) for partly completed machinery are documents which the manufacturer has drawn up and which remain on his premises (for more information, see Point 7 Internal documentation) because these also contain his relevant technical know-how. Only the conformity declaration, operating instructions, declaration of incorporation and installation instructions are supplied to the customer with the products.

The conformity assessment procedure is a means for the manufacturer to ensure that the machinery conforms to the requirements of the Machinery Directive. Annex VIII also sets out the "procedure" and creates the link with the necessary documentation (technical documentation).

Extract from Annex VIII of the Directive:

**Assessment of conformity** with internal checks on the manufacture of machinery

1. This Annex describes the procedure by which the manufacturer or his authorised representative who carries out the obligations laid down in points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of this directive.

2. For each representative type of the series in question, the manufacturer or his authorised representative shall draw up the technical files referred to in Annex VII, part A.

3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and the requirements of this Directive.
3. **External documents**

3.1 **Declaration of conformity and declaration of incorporation**

The new Machinery Directive controls the (minimum) content of the Declaration of Conformity and Declaration of Incorporation in Annex II. The form and position of the content on the documents is a matter of choice.

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Fig. 10: Example of a Declaration of Conformity (Machinery)
Fig. 11: Example of a Declaration of Incorporation (Partly completed machinery)
3.2 Operating instructions and installation instructions

In the operating instructions (for sample, see Fig. 12) all the relevant stages of the life of a machine are taken into account. The instructions also give information on relevant residual risks.

Fig. 12: Example of Instructions - Operating instructions

Description of
- Transport, packing
- Installation
- Commissioning
- Setting and tooling
- Normal operation
- Maintenance and cleaning
- Maintenance (trouble-shooting and fault elimination)
- Dismantling and disposal

DANGER denotes situations which can lead to severe injuries if safety precautions are not observed.
WARNING denotes situations which can lead to death if safety precautions are not observed.
CAUTION denotes situations which can lead to property damage if safety precautions are not observed.
NOTICE denotes situations which can lead to damage to property or the environment.

General Safety Precautions

Maintenance work is to be carried out only by trained personnel.

The safe operation of this unit can only be ensured if it is used for the purpose it was intended. If there is any question about the use, please contact the manufacturer. The manufacturer will not accept responsibility for damages resulting from misuse of this equipment.

The following applies to all work performed using the unit: adherence to pertinent national regulations pertaining to accident prevention and safety at the workplace in addition to any applicable internal rules and regulations of the owner/operator, even though they are not specifically cited herein.

Leaks of dangerous materials must be properly collected and disposed of so as not to harm any persons or the environment. The corresponding statutory regulations are to be followed.
To some extent the installation instructions for partly completed machinery also provide further information (Fig. 13), and are not just confined to installation.

Fig. 13: Example of installation instructions with user information
4. Standards in hydraulics

Standards regulate technical issues and represent the state-of-the-art in many technical areas. In this connection there are two essential aspects, the performance and safety.

EN 982 (Safety of machinery, Safety requirements of fluid power systems and their components, Hydraulics) and DIN 24346 (Hydraulic fluid power, Hydraulic systems, General rules for application) serve as a basis when the machinery is not a specific individual machine such as a machine tool, for which the relevant Type C standards are available (e. g. EN 693 Safety – Hydraulic Presses). Currently the draft EN ISO 4413 incorporates Hydraulic fluid power, General rules and safety requirements for systems and their components. It is however not yet implemented as a standard and has not yet been published in the Official Journal of the EU.

Within the Company Group, these standards are implemented in the form of HYDAC Works Standards (HN 25-01 and HN 25-02).

To date there is no individual product safety standard for hydraulic components. Basic safety requirements are covered by the application of the following standards in the Company Group.

Type A:
EN ISO 14121 Part 1 Risk assessment
EN ISO 12100 Part 1 and 2 General Principles for Design

Type B:
EN 982 Safety requirements for fluid power systems and their components - Hydraulics.
EN 983 Safety requirements for fluid power systems and their components - Pneumatics
EN IEC 60204 Electrical Equipment of Machines
EN 954 Part 1 Safety-related parts of control systems – Design, or
EN 13849 Part 1 and 2 Safety-related parts of control systems – General principles of design
DIN 24346 Just general rules for application!

If pressure equipment is also involved, harmonised standards according to the Pressure Equipment Directive 97/23/EC, such as those listed below, shall also be taken into consideration.

EN 13445 Part 1 to 8 Unfired pressure equipment
EN 14359 Hydraulic accumulators for hydraulic applications

If there are no harmonised standards or they are missing, or they do not exist for a product, then the design engineer must use (appropriate) national or international standards or specifications.
5. Risk assessment - (from risk analysis to risk avoidance)

The risk assessment is explained in Recital 23 of the Machinery Directive and is introduced via the General Principles given in Annex I. The risk assessment is therefore an elementary component of the conformity assessment procedure of the (machinery) manufacturer and forms part of the internal documentation, i.e. it is a component of the technical file for machinery and the relevant technical documentation for partly completed machinery.

In order to carry out a risk assessment, there are different procedures (see Information Annex B for the former harmonised standard EN 1050 - Safety of machinery. Risk assessment. Principles, B.1 to B.8).

- **PHA** Preliminary Hazard Analysis
- **WHAT-IF** Method
- **FMEA:** Failure Mode and Effects Analysis
- **FTA:** Fault Tree Analysis
- Fault Simulation for Control Systems
- **MOSAR:** Method Organized for a Systematic Analysis of Risks
- **DELPHI:** DELPHI Method
  Survey conducted amongst a group of experts

The text of the machinery directive itself does not set out specific requirements on this point. EN ISO 14121 Part 1 (formerly DIN EN 1050) is introduced as state-of-the-art for the Machinery Directive using the guidelines and the harmonised standards of the Official Journal of the EU. The annex of the standard contains a check-list of possible risks. The basic Works Standard is HN 18-01 (adoption of EN ISO 14121-1).

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**Fig. 14: Flow chart of the risk assessment**

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**Procedure for the design engineer in system design**

1. **Start**
2. Determine system limits
3. Hazard identification
4. Risk estimation
5. Risk evaluation
6. Is the machine adequately safe?
   - No: Risk reduction necessary
   - Yes: End

EN 1050 and EN ISO 14121
6. SIL or PL – Safety-related parts for control systems

Functional Safety

A control system can initiate, or cannot prevent, a hazard-causing movement. Therefore control systems of machines must also be included in the risk assessment. These control systems are constructed of individual components, in this case therefore safety-related parts (SRP/CS - Safety Related Part of a Control System). In this context this is also known as functional safety, i.e. a safety function is fulfilled. A control system can ultimately include one or several safety functions. The components which are built into a control system are themselves not necessarily always part of a control system or even safety components (see Fig. 20). If they are however built into a control system, they affect the reliability of the whole control system on the basis of their reliability.

To assess control systems, there are two options:

![Fig. 15: Assignment of standards to machine controls](image)

For hydraulic or electrohydraulic control systems, EN 954-1, or its successor EN 13849-1, is applied because the hydraulics are not covered by the electrotechnical standards EN IEC 62061 (based on EN IEC 61508) (see Fig. 15). The "BGIA Report 2/2008 Functional Safety of Machine Controls – Application of DIN EN ISO 13849 –“ describes in detail the application of EN ISO 13849.

A typical parameter for components which are to be used in controls is the MTTFd (Mean Time to Dangerous Failure) or also B10d for electrotechnical components (in this case the MTTFd depends on the number of cycles). They represent an equipment characteristic type or a "quality standard" (see Fig. 16 and Table 2). These are values for the statistical probability of the failure of components (Table 3) and are inversely proportional to the failure rates.

\[ \text{MTTFd} = \frac{1}{\lambda_d} \]
The necessary calculations can be made using the free software SISTEMA from BGIA (a research/testing institution based in Germany) (http://www.dguv.de/bgia/en/pra/en13849/index.jsp). This software contains the mathematical models/interfaces for the components.
A machine builder also determines the PLr (required Performance Level) from the risk graphs. Based on the reliability of the components (MTTFd or B10d values of the manufacturer or values from the table for the Standard EN ISO 13849-1*) the actual PL of the planned control system can be determined. PL must always be greater than or equal to PLr.

The control systems are represented in EN ISO 13849-1 in the form of categories; in other words they are available as designated system architectures.

<table>
<thead>
<tr>
<th>Mechanical components</th>
<th>Tables A.1 and A.2</th>
<th>–</th>
<th>MTTFd = 150</th>
</tr>
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<tbody>
<tr>
<td>Hydraulic components</td>
<td>Tables C.1 and C.2</td>
<td>EN 982</td>
<td>MTTFd = 150</td>
</tr>
<tr>
<td>Pneumatic components</td>
<td>Tables B.1 and B.2</td>
<td>EN 983</td>
<td>B10d = 20 000 000</td>
</tr>
<tr>
<td>Relays and contactor relays with negligible load</td>
<td>Tables D.1 and D.2</td>
<td>EN 20205, IEC61810, IEC60947</td>
<td>B10d = 20 000 000</td>
</tr>
<tr>
<td>Relays and contactor relays with maximum load</td>
<td>Tables D.1 and D.2</td>
<td>EN 20205, IEC61810, IEC60947</td>
<td>B10d = 400 000</td>
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<tr>
<td>Emergency stop devices when used in areas exposed to low environmental contamination, e.g. in laboratories a)</td>
<td>Tables D.1 and D.2</td>
<td>IEC60947, ISO 13850</td>
<td>Fault exclusion up to 100 000 cycles, provided manufacturer's certification is available</td>
</tr>
<tr>
<td>Emergency stop devices when used in areas exposed to normal environmental contamination, e.g. on machinery a)</td>
<td>Tables D.1 and D.2</td>
<td>IEC60947, ISO 13850</td>
<td>Fault exclusion up to 6 050 cycles</td>
</tr>
<tr>
<td>Enabling switches (3-stage) irrespective of the load a)</td>
<td>Tables D.1 and D.2</td>
<td>IEC 60947</td>
<td>Fault exclusion up to 100 000 cycles</td>
</tr>
</tbody>
</table>

* The parameter data from EN ISO 13849-1 for individual components can be applied if the conditions from EN ISO 13849-2 and the manufacturer's data are complied with.

Table 2: Typical reliability parameters of components

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* Trial and tested safety principles according to DIN EN ISO 13849-2:2003

** Typical values:**
- MTTFd (years)
- B10d (cycles)
- Fault exclusion

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![Diagram](image-url)
Fig. 19: System example of a "complete" control system

Fig. 20: Example of a system of valves as a hydraulic control system (subsystem)
Fig. 21: SISTEMA user interface  
(calculation of parameters and input of parameters)

<table>
<thead>
<tr>
<th>Designation of the $MTTF_d$ for each channel</th>
<th>Range of the $MTTF_d$ for each channel</th>
</tr>
</thead>
<tbody>
<tr>
<td>low</td>
<td>3 years $\leq MTTF_d &lt; 10$ years</td>
</tr>
<tr>
<td>medium</td>
<td>10 years $\leq MTTF_d &lt; 30$ years</td>
</tr>
<tr>
<td>high</td>
<td>30 years $\leq MTTF_d &lt; 100$ years</td>
</tr>
</tbody>
</table>

Table 3: Ranges for the reliability of control channels

Fig. 22: Reliability in years – MTTFd values
7. Internal documentation

The Machinery Directive sets out in Annex VII which documentation is required. It lists the technical file for machinery and the essential technical documentation for partly completed machinery (see Table 4). The majority of the documentation remains at the manufacturer's premises and on reasoned request must be made available to the relevant supervisory authority within a reasonable time period. These will be documents which for the most part come up in any case within the context of design work. In addition, the directive requires that there must be an authorised person for documentation (person authorised to compile technical documentation).

Extract from Annex VII of the Directive:

A. Technical file for machinery

This part describes the procedure for compiling a technical file. The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. The technical file must be compiled in one or more official Community languages; except for the instructions for the machinery, for which the special provisions of Annex I, section 1.7.4.1 apply.

1. The technical file shall comprise the following:
   a) a construction file including:
      – a general description of the machinery,
      – the overall drawing of the machinery and drawings of the control circuits as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,
      – full detailed drawings, accompanied by any calculation notes, test results, certificates etc., required to check the conformity of the machinery with the essential health and safety requirements,
      – the documentation on risk assessment demonstrating the procedure followed, including:
         i) a list of the essential health and safety requirements which apply to the machinery,
         ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,
      – the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
      – any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
      – a copy of the instructions for the machinery,
      – where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,
      – where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,
      – a copy of the EC declaration of conformity;
b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive. The manufacturer must carry out necessary research and tests on components, fittings or the completed machinery to determine whether by its design or construction it is capable of being assembled and put into service safely. The relevant reports and results shall be included in the technical file.

2. The technical file referred to in point 1 must be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced. The technical file does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available with a period of time commensurate with its complexity by the person designated in the EC declaration of conformity. The technical file does not have to include detailed plans or any other specific information as regards the subassemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.

3. Failure to present the technical file in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.

B. Relevant technical documentation for partly completed machinery

This part describes the procedure for compiling relevant technical documentation. The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for this assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages. It shall comprise the following:

a) a construction file including:
   – the overall drawing of the partly completed machinery and drawings of the control circuits,
   – full detailed drawings, accompanied by any calculation notes, test results, certificates etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,
   – the risk assessment documentation demonstrating the procedure followed, including:
     i) a list of the essential health and safety requirements applied and fulfilled,
     ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,
     iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
     iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
     v) copy of the assembly instructions for the partly completed machinery;
b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.

The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical documentation.

The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.

Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.

<table>
<thead>
<tr>
<th>Type</th>
<th>M a c h i n e y</th>
<th>Partly completed machinery</th>
</tr>
</thead>
<tbody>
<tr>
<td>General description of the machinery</td>
<td>X</td>
<td>–</td>
</tr>
<tr>
<td>Overall drawing</td>
<td>X</td>
<td>–</td>
</tr>
<tr>
<td>Full detailed drgs, poss. with calcs</td>
<td>X</td>
<td>–</td>
</tr>
<tr>
<td>Documents for risk assessment: list of essential health and safety requirements</td>
<td>X</td>
<td>–</td>
</tr>
<tr>
<td>Documents for risk assessment: description of risk avoidance, risk reduction</td>
<td>X</td>
<td>–</td>
</tr>
<tr>
<td>Applied standards, specifications, ...</td>
<td>X</td>
<td>–</td>
</tr>
<tr>
<td>Technical reports with test results</td>
<td>X</td>
<td>–</td>
</tr>
<tr>
<td>Copy of the operating instructions</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Copy of the installation instructions</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Where necess. copies of incorporation decl. &amp; conformity decl. for bought-in prod.</td>
<td>X</td>
<td>–</td>
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<td>(Copy) Decl. of conformity</td>
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<tr>
<td>Declaration of Incorporation</td>
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</tr>
<tr>
<td>List of measures to ensure conformity with the Directive</td>
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</tr>
</tbody>
</table>

Table 4: Overview of internal and external manufacturer's documentation
Die neue EG-Maschinenrichtlinie 2006


Autoren:
Koll, Th., Klaus, Th., Olek, M., H., von Loefen, D.

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2.1. Anwendungbereich
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