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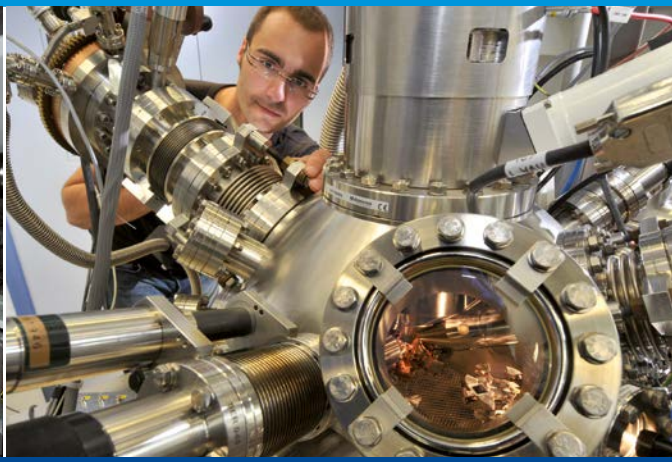

Information guide

Manufacturing and operation of equipment designed for research purposes

CE conformity and workplace safety

December 2012

Imprint
Published by:
Deutsche Gesetzliche
Unfallversicherung e.V. (DGUV)

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This guide was produced by the Helmholtz Association and the VBG (German Social Accident Insurance Institution for the Administrative Sector, acting as the lead organisation) in consultation with the DGUV's working group on higher education institutions. We would like to take this opportunity to thank the experts involved for their help and their input.

HELMHOLTZ
GEMEINSCHAFT

Further information on the Helmholtz Association can be found in Section 9.

Layout & design:
Deutsche Gesetzliche Unfallversicherung e.V. (DGUV), Media Production Department

Published in December 2012
(The present document is the English translation of the German BGI/GUV-I 5139,
of October 2011)

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Contents

1 Introduction

Research facilities, especially large research centres, construct and operate buildings and equipment to be used for research purposes.

In the numerous laboratories, pilot facilities and installations in fields where the line between distinct areas of research and technology is blurred, the protective measures that have to be taken sometimes differ from the usual measures. This is because the research buildings/equipment use new approaches that do not always allow the customary solutions to be implemented. Indeed, some cases call for the „state of the art" to be redefined. The existing legislation governing equipment and product safety and workplace safety does not completely cater for the special requirements prevalent in research activities. In particular, the 9th Ordinance concerning the „Produktsicherheitsgesetz" (Product Safety Act, abbreviated to „ProdSG" in German), the ordinance with which the Machinery Directive is transposed into German law, needs to provide more specific detail on this aspect.

This document aims to provide guidance for managerial staff on how to meet the legal requirements whilst also taking into account the conditions specific to research and development settings.

2 Definitions

Manufacturer/distributor

As defined by law, the managing directors or board members are the manufacturer/distributor of equipment designed for research purposes. Duties arising from this responsibility can be transferred in writing to reliable and competent persons.
The legal requirements are set out in Product Safety Act (abbreviated to „ProdSG" in German) and the ordinances relating to it.

The ProdSG stipulates safety requirements for products and equipment, which manufacturers/distributors of machinery, electrical equipment, pressure equipment and other equipment are obliged to observe. In accordance with the EU Machinery Directive, manufacturers and importers of machinery and equipment (including safety components) are responsible for conformity. A declaration of conformity (Annex 1) and a CE mark on the product or, in the case of partly completed machinery, a declaration of incorporation (Annex 2) serve as confirmation by the manufacturer that its machinery/equipment meets the requirements of the applicable EU directives. In certain cases, conformity has to be assessed by external bodies but usually the manufacturers issue the declarations themselves.

Operator

The managing directors or board members are deemed to be the operators of equipment designed for research purposes. Consequently, they are responsible by law for occupational health and safety. Duties arising from this responsibility can be transferred in writing to reliable persons who are competent in the specific field concerned.
The legal requirements are set out in the"Arbeitsschutzgesetz" (Act on Occupational Safety and Health) and the „Betriebssicherheitsverordnung" (Ordinance on Industrial Safety and Health, abbreviated to „BetrSichV" in German).

The BetrSichV stipulates requirements regarding the safe operation and periodic inspection of work equipment and devices requiring special monitoring.

Use

With regard to mechanical devices, the term „use" covers all of the activities shown in the diagram below, arising in connection with the use of the mechanical device. Its clearly defined intended use is specified in the operating instructions.

The safe state of the mechanical device is required to be maintained during use. Damage can be identified in good time, enabling action to be decided on and carried out, by means of inspections.

The risks involved in using the device are determined and assessed with the help of a user risk assessment, taking into account the specific operating methods, and the necessary protective measures are then identified.

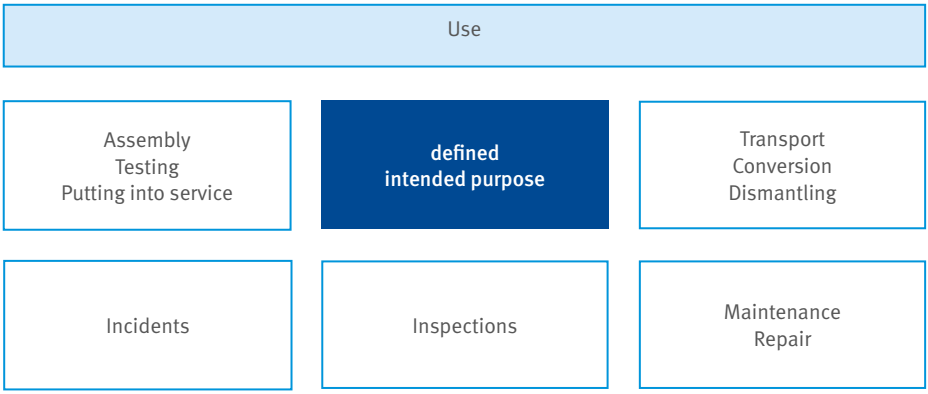

Fig. 1 Phases of use

Manufacturer risk assessment

This assessment has to be carried out by the manufacturer of the equipment. It comprises a risk analysis, risk evaluation, the resulting measures to reduce risk and identification of the residual risks (cf. DIN EN ISO 12100). The residual risks are documented in the operating instructions. The manufacturer risk assessment only covers the risks posed by a piece of

equipment. Any additional hazards due to interaction between the equipment and other factors during operation must be recorded in the operator's risk assessment.

User/operator risk assessment

The operator of the equipment is responsible for this assessment. It covers all hazards arising during use, the residual risks described in the instructions and any hazards arising from the work environment. The operator must also keep a record of the findings of the assessment, the measures the operator has identified as necessary and the results of activities to monitor compliance with the measures.

Notified bodies

A „notified body" is a public or private technical body, which the relevant authorities at federal-state level (Germany is divided into 16 federal states) have accredited and declared to the „Bundesministerium für Arbeit und Soziales" (Federal Ministry of Labour and Social Affairs). Notified bodies' role in the conformity assessment is either to approve and monitor the manufacturer's quality assurance system or to perform product testing.

Authorised inspection bodies

As opposed to notified bodies, authorised inspection bodies are accredited to conduct periodic inspections of equipment requiring special monitoring (including the inspections performed prior to the equipment being put into service for the first time or recommissioning), in accordance with Section 17 of the Product Safety Act (abbreviated to „ProdSG" in German). This includes, for example, inspection of pressure equipment, which, due to the pressure-volume product, is no longer allowed to be inspected in house.

The state (in the shape of the health and safety agencies and the inspection service) withdrew from the field of inspection of equipment requiring special monitoring in 2008, thus liberalising this inspection business. As a result, other bodies and engineering firms are now also accredited as testing bodies.

Qualified persons

The Ordinance on Industrial Safety and Health („BetrSichV") replaces the former „expert" („Sachverständiger"/"Sachkundiger") with the concept of a „qualified person". A qualified person is someone whose training, experience and recent professional activity give them the expertise necessary to inspect work equipment. The requirements for qualified persons are specified in detail in the „Technische Regeln für Betriebssicherheit" (Technical Rules for Industrial Safety). They cover general requirements for qualified persons plus additional qualifications required in work environments where there are explosion/pressure hazards.

Where a device has to be inspected by a notified body, responsibility for correct inspection lies with the accredited organisation commissioned to perform the inspection work, i.e. the notified body.

3 Organisation

The Machinery Ordinance does not specify which particular organisational measures should be taken to ensure that only machinery that meets the legal requirements is placed on the market. The employer is responsible for the conformity procedure. The employer or a person authorised by him/her signs the decalartion of conformity. The declaration also specifies the person responsible for the technical documentation.

A pragmatic approach is to appoint one person (CE coordinator or CE officer) to be in charge of ensuring consistent compliance with the requirements of the Product Safety Act („ProdSG"). The role of CE coordinator or CE officer necessitates special knowledge and has to be embedded in the enterprise's organisational structure. It is thus a responsible position and that responsibility can only be fulfilled by someone with the necessary expertise.

The various areas of responsibility in the manufacturing process should be documented. A signature card of the kind depicted in Annex 4 can be used for this purpose.

The tasks described in this section are not part of the duties to be performed by the safety specialist defined in the Occupational Safety Act (abbreviated to „ASiG" in German). If the safety specialist does perform one of the above-mentioned functions, it should by clearly defined in a job profile and should be seen as distinct from his or her tasks as a safety specialist.

4 Legally compliant procurement and manufacturing

The preconditions for legal compliance are defined in the ProdSG and include a declaration of conformity/incorporation.

Equipment specifically designed and built for research purposes and intended for temporary use (see Section 6) in laboratories only is exempt from the Machinery Ordinance.

> **N. B.:** Equipment designed for research purposes is often subject to a lengthy, ongoing development process. Safe research activity in line with the health and safety and accident-prevention regulations must be guaranteed during that process but a declaration of conformity as required by the ProdSG is not necessary**.**

If equipment designed for research purposes, or parts thereof, has/have to be relocated as part of a joint experimental development project and ownership changes as a result, a declaration of conformity/incorporation is required.

The principles laid out in Annex 8 and Section 6 must be applied when procuring or manufacturing equipment designed for research purposes.

5 Procurement of scientific equipment from non-EEA states

If equipment is purchased from outside the European Economic Area (EEA), the purchase contract should stipulate that the manufacturer must meet the EEA requirements and conduct the conformity procedure.

If this is not possible, the research institute, being the entity that places the equipment on the EEA market (i.e. the distributor), is responsible. It must provide evidence of conformity and produce the declaration of conformity (in other words, conduct the „conformity procedure").

In the case of equipment designed for research purposes that does not meet European Community directives and for which the conformity procedure cannot be conducted, the operator must observe the German health and safety and accident-prevention regulations and guidelines. The equipment must be inspected by a qualified person appointed by the operator or by an independent testing body before being put into service. Equipment specifically designed and built for research purposes only and intended for temporary use (see Section 6) in laboratories is exempt from the Machinery Ordinance.

6 In-house manufacturing of equipment designed for research purposes

The procedure below must be followed for equipment manufactured in house and designed for research purposes only.

6.1 Classifiy the equipment:

- Which ProdSG ordinance applies?
- Is CE marking necessary?
  If yes: follow steps 6.2 – 6.7
  If no: follow steps 6.2 – 6.6

  6.1.1. The Machinery Ordinance (9th Ordinance concerning the ProdSG Product Safety Act) does not apply to machinery specifically designed and built for research purposes and intended for temporary use in laboratories.

6.2 Conduct the risk assessment (in accordance with DIN EN ISO 12100, for example)

6.3 Identify the standards to be applied and apply them (selection of materials, dimensioning, safety components, etc.)

6.4 Compile technical documentation (Annex 9), which then remains with the manufacturer

6.5 If appropriate, bring in a notified body (see glossary and Annex IV of the Machinery Directive)

6.6 Draw up operating instructions (or assembly instructions in the case of partly completed machinery) and give them to the operator. The operating instructions must be written in languages acceptable to the operator and understandable for the users. The languages required must be specified in a contract.

6.7 Produce declaration of conformity/incorporation and get it signed (employer) and affix the CE mark if required (Annexes 1 and 2).

When obtaining the signature, it is useful to conduct a formal check as well as the technical inspection (Annex 5).

The person responsible for the in-house manufacturing must ensure that this procedure is adhered to. Responsibilities for the technical implementation of each design and manufacturing phase should be documented in writing. The conformity procedure described must also be adhered to in the case of collaboration agreements.

The documents specified in 6.2 – 6.6 must always be produced.

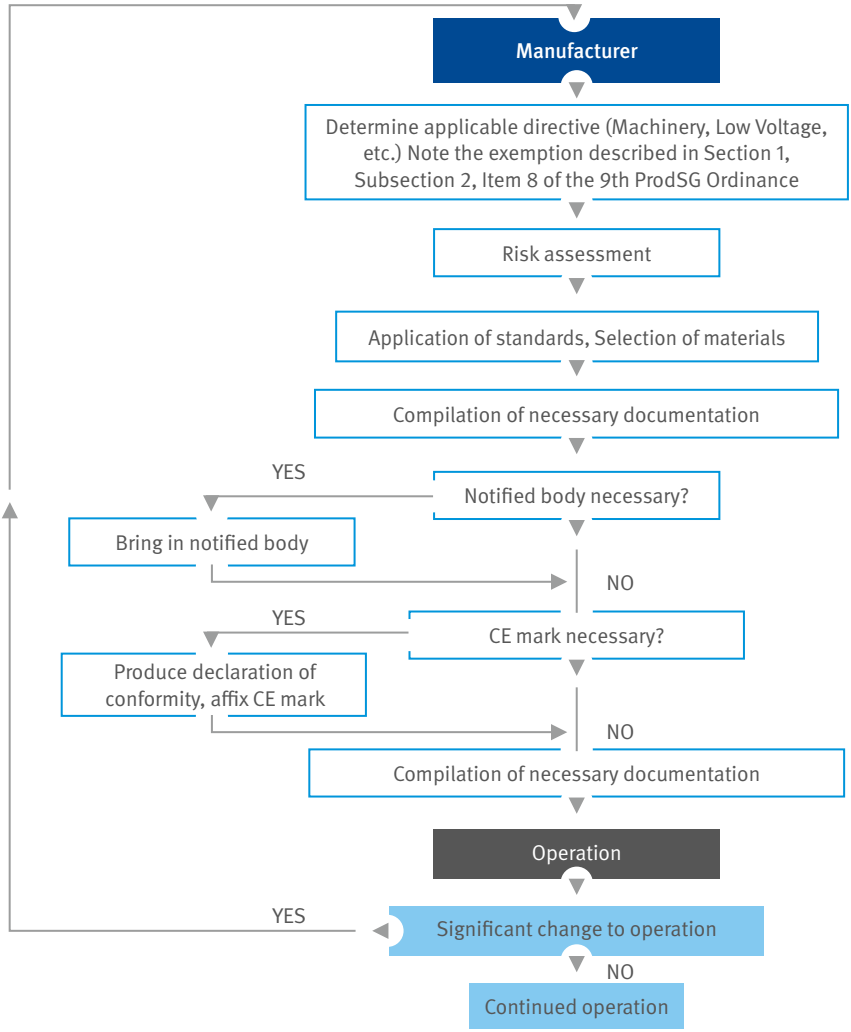

Fig. 2 Flow chart for manufacturing equipment designed for research purposes

Where experiments use very different components/subassemblies, the following distinctions must be made:

Testing devices (e.g. motorised specimen holders), are produced as prototypes or in small quantities. Such facilities could be support devices, assemblies or modified series-produced parts that are used in a pre-experimental set-up. The question of whether certification is required has to be decided on a case-by-case basis. One of the criteria, for instance, is whether there is a risk of force occurring (see DIN EN 12453: maximum force of 150 N on a test area 80 mm in diameter) or whether there are any electrical hazards present (maximum touch voltage 50 V alternating voltage).

Add-on parts are series-produced parts (pumps, drives, power packs, etc.) purchased from an industrial manufacturer plus add-on parts that are clearly definable as machinery. They always require CE certification. Add-on parts also include laboratory and workshop equipment, such as machine tools, appliances and measuring instruments.

Please take note of the following with regard to „equipment specifically designed and built for research purposes and intended for temporary use (see the 9th Ordinance concerning the ProdSG Product Safety Act).

Temporary use in the laboratory means „not permanent“. The main factor to be considered here is the overall duration of the experiment. Generally speaking, „temporary” is taken to mean a period of no more than three years.

The term „**laboratories** in research facilities“ is taken to mean not only laboratories in the narrow sense (cf. the “Working Safely in Laboratories” information guide (BGI/GUV-I 850-0)) but also other areas (buildings or sites) in which experiments are carried out. Such areas might be, for example, large-scale laboratories (Fig. 3), buildings for experiments and particle accelerators (Fig. 4 and 5) or sites used for fieldwork and outdoor experiments (Fig. 6).

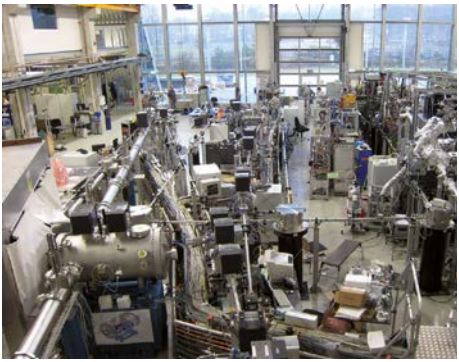

Fig. 3 Large-scale experimental hall

Fig. 4 Building for S3 experiments

Fig. 5 Particle accelerator

Fig. 6 Polar research station

7 Other legislation and ordinances

EMC Act (EMC Directive 2004/108/EC)

Though declarations of conformity and CE marks are not required for fixed installations due to their special nature, the installations do have to meet the protection requirements. This is normally the case if the individual components are CE-certified and have been assembled in accordance with good electrical engineering practice. If the individual components are intended to be incorporated into a fixed installation and are not commercially available, they do not have to be CE-certified. However, there must be instructions and precautions in place to ensure that the equipment can be operated in accordance with the EMC law when the component has been incorporated. For further details, see the EMC guide produced by Germany's Federal Network Agency.

Low Voltage Ordinance (1st Ordinance concerning the ProdSG Product Safety Act) (implementing Directive 2006/95/EC)

The Low Voltage Ordinance applies to electrical equipment used with a rated voltage:

- between 50 and 1,000 V in the case of an alternating current,
  and
- between 75 and 1,500 V for a direct current.

The above-mentioned voltage ranges refer to the rated input and output voltage of the equipment. The voltages inside may be higher than the rated voltage.

Pressure Equipment Ordinance (14th Ordinance concerning the ProdSG Product Safety Act) (implementing Directive 2009/105/EC)

The Pressure Equipment Ordinance applies unconditionally to equipment designed for research purposes. The content of the necessary documentation is presented in Annex 9.

Further legislation and ordinances that can be applied:

- Medical Devices Act (abbreviated to „MPG“ in German)
  (implementing Directive 93/42/EEC and others)
- Simple Pressure Vessels Ordinance (6th Ordinance concerning the ProdSG)
  (implementing Directive 2009/105/EC)
- Explosion Protection Ordinance (11th Ordinance concerning the ProdSG)
  (implementing Directive 94/9/EC)

8 Operation of equipment designed for research purposes

The Ordinance on Industrial Safety and Health (abbreviated to “BetrSichV” in German) stipulates requirements regarding the safe operation and periodic inspection of work equipment and devices requiring special monitoring.

Irrespective of the conformity procedure, the operator must perform the following tasks in order to ensure safe operation of the machinery and equipment (see Annex 6):

- produce a risk assessment, including the documentation,
- produce any necessary instructions (in different languages if needed) and
- brief or instruct the workers.

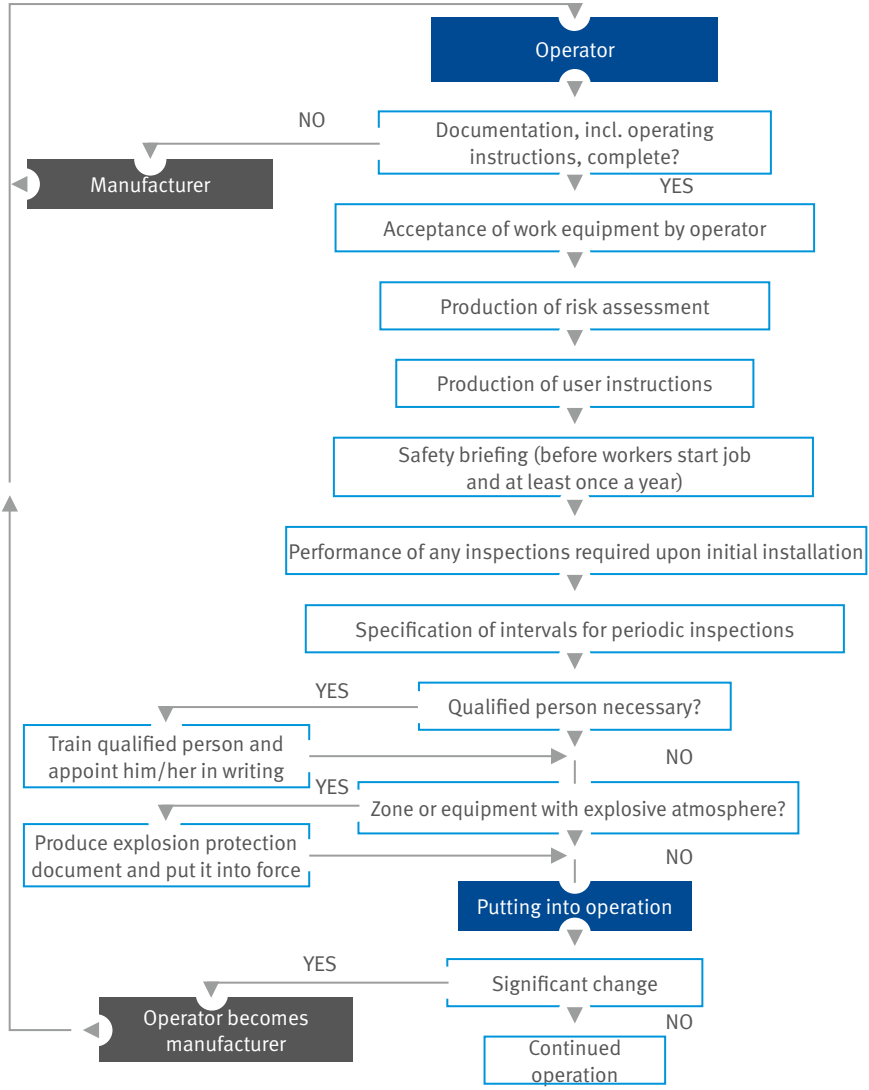

Fig. 7 Flow chart for operation of equipment designed for research purposes

In addition, the operator has to specify periodic inspection intervals and conduct the inspections at the specified times.

Equipment examinations/inspections in accordance with the ProdSG and BetrSichV

Examination/ inspection	Who`s responsible	What`s covered	Who does it?	When?
Conformity assessment	Manufacturer	Products and equipment requiring special monitoring as defined in the ProdSG; the relevant ones are, for example: • machinery, • pressure equipment and • electrical equipment.	Manufacturer or notified body*	Before declaration of conformity is issued
Certification assessment	Manufacturer	Particularly dangerous devices (see 6.5)	Notified body	Before declaration of conformity is issued
Inspection prior to putting into service	Operator	Equipment requiring special monitoring as defined in Section 1(2) of the BetrSichV**	Qualified person or authorised inspection body*	Prior to equipment being put into service
Periodic inspection	Operator	Equipment requiring special monitoring and other work equipment depending on the hazard potential	Qualified person or authorised inspection body*	At intervals to be specified (maximum intervals are stipulated in some cases)
Inspection following the equipment being decommissioned or following a significant change	Operator	Equipment requiring special monitoring depending on the hazard potential	Qualified person or authorised inspection body*	Prior to resumption of service

* Where certain limit values are exceeded

** E.g. steam boilers, pressure equipment, pressure lines, lifts, storage facilities and tanks for combustible liquids, lift systems and equipment in areas where there is a risk of explosion

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10 Annexes

Annex 1: **Sample EC Declaration of Conformity**

Annex 2: **Sample EC Declaration of Incorporation**

Annex 3: **Sample assembly instructions for partly completed machinery**

Annex 4: **Sample signature card for EC Declarations of Conformity**

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Annex 9: **Comparison of the EU directives covering equipment and product safety and the national laws transposing them**

Annex 1

Sample EC Declaration of Conformity in accordance with the EC Machinery Directive 2006/42/EC

Manufacturer/authorised representative

_____

_____

_____

_____

We hereby declare that the following work equipment:

Denomination/make: _____

Type: _____

Serial no.: _____

year of manufacture: _____

conforms to the following directives:
EC Machinery Directive 2006/42/EC
Pressure Equipment Directive 97/23/EC.

The protection objectives of the Electromagnetic Compatibility Directive, 2004/108/EC were adhered to for this one-off, fixed installation by using components that conform to the directives and by assembling them in accordance with DIN EN ISO 60204-1: 2006. The protection objectives of the Low Voltage Directive, 2006/95/EC, were adhered to in accordance with Annex I, No. 1.5.1 of the Machinery Directive, 2006/42/EC.

The following standards were applied:

DIN EN ISO 12100	**Safety of machinery**
DIN EN 60204	**Electrical equipment of machines**
DIN EN ISO 13849-1	**Safety of machinery – Safety-related parts of control systems**

The person appointed to manage the technical file is (name and address):

Signatory's details:

Name: _____

Position: Employer/authorised person

_____

Date, signature

Annex 2

Sample EC Declaration of Incorporation in accordance with Annex II, 1B of the EC Machinery Directive 2006/42/EC

Manufacturer/authorised representative

_____

_____

_____

_____

Description of the machinery:

Denomination/make: _____

Type: _____

Serial no.: _____

Year of manufacture: _____

We hereby declare that the following essential requirements of Machinery Directive 2006/42/EC have been met:

1.3.7.; 1.5.1.; 1.5.10.; 1.5.16.; 1.5.2.; 1.6.3.; 6.4.3.

Furthermore, we declare that the relevant technical documentation specified in Annex VII, Part B, has been compiled and that the partly completed machinery complies with the provisions of the following EC directive:

2004/108/EC: Electromagnetic compatibility

The manufacturer/authorised representative undertakes to transmit, in response to a reasoned request by the national authorities, the relevant documentation concerning the partly completed machinery. Said transmission shall be by post or in the form of an e-mailed PDF file. This undertaking shall be without prejudice to the manufacturer's intellectual property rights.

Important notice:
The 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 provisions of this directive, where appropriate.

Person appointed to manage the technical documentation (name and address):

Signatory's details:	
Name:	_____
Position:	Employer/authorised person
	_____
	Date, signature

Annex 3

Sample assembly instructions for partly completed machinery in accordance with Annex VI of the EC Machinery Directive 2006/42/EC

Manufacturer/authorised representative

_____

_____

_____

_____

_____

Description of the machinery:

Denomination/make: _____

Type: _____

Serial no.: _____

Year of manufacture: _____

Conditions which must be met with a view to correct incorporation in the final machinery, combined with other parts, so as not to compromise safety and health:

Condition 1:

Condition 2:

Condition 3:

Etc.

Signatory's details:	
Name:	_____
Position:	Employer/authorised person
	_____
	Date, signature

Annex 4

Sample signature card for EC Declarations of Conformity

Please sign the appropriate box to confirm that you are responsible for and have fully completed the task concerned for

Machine/equipment: Type: _____

Year of construction: _____ Serial number: _____

Task	Required? (Yes/No)	Name	Position	Date	Signature
Selection of directives to be applied					
Risk evaluation (risk assessment/safety strategy), selection of and conformity with standards					
For the electrical engineering					
For the hydraulics					
For the pneumatics					
For the controls					
For the mechanical design					
For the mechanical production					
Production of documentation					
Inclusion of notified body (Annex IV of the Machinery D, Pressure Equipment D, etc.)					
Monitoring and objective assessment of the procedure by the coordinator responsible in the organisational unit (Documentation of project responsibility)					
Monitoring and formal assessment of the procedure by the line manager of the coordinator in the organisational unit (Documentation of line management responsibility)					

Annex 5

Checklist
for formal assessment of the EC conformity procedure

	Yes	No
Applicable directives		
Machinery Directive	☐	☐
Low Voltage Directive	☐	☐
Electromagnetic Compatibility Directive	☐	☐
Pressure Equipment Directive	☐	☐
_____	☐	☐
_____	☐	☐

	Yes	No	N/A
Technical work equipment, experiments, machinery, safety components, etc.			
• Ready for use	☐	☐	☐
• Still being developed	☐	☐	☐
• Is used in research centre	☐	☐	☐
• Is used outside research centre	☐	☐	☐
• Might be provided to third parties	☐	☐	☐
• Might be sold to third parties	☐	☐	☐

	Yes	No	N/A
Risk assessment			
• Risk analysis has been produced	☐	☐	☐
• Risk has been evaluated	☐	☐	☐
• Protective measures have been described and implemented	☐	☐	☐

Instructions	Yes	No	N/A
• Assembly	☐	☐	☐
• Installation	☐	☐	☐
• Operation and Maintenance	☐	☐	☐
• Breakdown	☐	☐	☐
• Decommissioning	☐	☐	☐
• Disposal	☐	☐	☐
• Drawings	☐	☐	☐
• Circuit diagrams	☐	☐	☐
• Standards	☐	☐	☐
• Required inspections for installation and operation	☐	☐	☐
The CE procedure has been conducted in accordance with the directive(s); a CE mark will be affixed	☐	☐	

Comments:

Place and date of signature

Name, CE coordinator, signature

Annex 6

Operator's checklist

	Yes	No	N/A	
Operation				
• Risk assessment has been produced. It assesses the residual risks remaining from the risk assessment and the risks during operation and deals with the necessary protective measures	☐	☐		
• Operating instructions	☐	☐		
• User instructions	☐	☐	☐	
• Briefing (documented in writing, before workers start job, at least once a year)	☐	☐		
• Type plate with required information attached	☐	☐	☐	
• Inspections required upon initial installation carried out:				
Electrics	☐	☐	☐	
Pressure		☐	☐	☐
Explosion protection	☐	☐	☐	
_____	☐	☐	☐	
_____	☐	☐	☐	
• Periodic inspection intervals specified in writing	☐	☐	☐	
• Necessary qualified person appointed in writing	☐	☐	☐	

Name: _____ Qualification: _____

Name: _____ Qualification: _____

Name: _____ Qualification: _____

• Explosion protection document has been produced and put into force by means of signature	☐	☐	☐	
_____	☐	☐	☐	
_____	☐	☐	☐	

Operator (date, name, signature)

Annex 7

Sample signature card for the operator

Please sign the appropriate box to confirm that you are responsible for and have fully completed the task concerned for

machine/equipment:

Type:_____ Year of construction: _____

Serial number: _____

Task	Required? (Yes/No)	Name	Position	Date	Signature
Acceptance of machinery/ equipment by operator responsible	Yes				
Risk assessment in accordance with the BetrSichV (see "Hazard factors" checklist and record of results)	Yes				
Production of user instructions	Yes				
Briefing, which has to be documented in writing (before workers start the job, in the event of significant changes, at least once a year)	Yes				
Performance of inspections required upon initial installation					
Specification of intervals for periodic inspections					
Appointment of necessary qualified persons					
Production of explosion protection document					

Task	Required? (Yes/No)	Name	Position	Date	Signature
Declaration of consent to install machinery/equipment from laboratory/hall operator responsible					
Monitoring and objective assessment of the procedure by the coordinator responsible in the organisational unit (Documentation of project responsibility)					
Monitoring and formal assessment of the procedure by the line manager of the coordinator in the organisational unit (Documentation of line management responsibility)					

Annex 8

Information on procuring equipment designed for research purposes

Purchasing, hiring, borrowing, leasing and shared use

The aim is to procure equipment that has the technical and safety features identified during the selection process.

Procurement can take the following forms: purchasing, hiring, borrowing, leasing or shared use. In all of these forms, the procurement entails the supplier transferring possession of products as described in the Product Safety Act.

Procurement processes of this nature are usually based on performance specifications and examinations of the quote(s) plus a supplier evaluation. When the contract is awarded, a written record must be made of the fact that the equipment to be supplied must meet the relevant health and safety requirements.

In particular, relevant requirements for equipment designed for research purposes can be found in the:

- Product Safety Act (“ProdSG”),
- Ordinance on Industrial Safety and Health (“BetrSichV”),

and

- DGUV (German Social Accident Insurance) rules and regulations.

By taking on the contract, the supplier agrees to provide equipment that meets the requirements mentioned. The subsequent handover to the procuring party is concluded by means of **formal** and **technical acceptance** of the equipment and provision of the necessary **documentation**.

Formal acceptance check, covering

- Adherence to contractual stipulations,
- Completeness of equipment,
- Certificates verifying that any required testing has been performed,
- Marking,
- Marking, e.g. with the CE, VDE, GS or DGUV Test mark, shows that the equipment conforms to good engineering practice,
- EC declarations of conformity.

Technical acceptance check, covering

- All assured functions ,
- All assured features,
- All assured safety-related features.

Documentation check, covering

- Assembly and operating instructions ⇢ Language must be understood by user,
- Structural analysis and/or certificates,
- Technical drawings and circuit diagrams,
- Testing instructions and test criteria.

Key European directives concerning conformity assessment and the German laws transposing them		
EU directives	**Transposition into German law**	**Additional ordinances**
Low Voltage Directive 2006/95/EC	Product Safety Act (ProdSG)	Ordinance on the placing on the market of electrical equipment within certain voltage limits (1st Ordinance concerning the ProdSG)
Directive on simple pressure vessels 2009/105/EC		Ordinance on the placing on the market of simple pressure vessels (6th Ordinance concerning the ProdSG)
Machinery Directive 2006/42/EC		Machinery Ordinance (9th Ordinance concerning the ProdSG)
ATEX Directive 94/9/EC (ATEX)		Explosion Protection Ordinance (11th Ordinance concerning the ProdSG)
Pressure Equipment Directive 97/23/EC		Pressure Equipment Ordinance (14th Ordinance concerning the ProdSG)
Directives on the health and safety of workers 89/391/EEC 95/63/EG 2001/45/EC	Act on Occupational Safety and Health (ArbSchG)	Ordinance on Industrial Safety and Health (BetrSichV)

Annex 9

Comparison of the EU directives covering equipment and product safety and the national laws transposing them

Content of documentation as per Machinery Dir.	Content of documentation as per Low Voltage Dir.	Content of documentation as per Press. Equipt. Dir.
1. Declaration of conformity	**1. Declaration of conformity**	**1. Declaration of conformity**
2. Signature card (recommended)	**2. Signature card (recommended)**	**2. Signature card (recommended)**
3. Description of function	**3. Instructions** 3.1 General description of the work equipment 3.2 Assembly 3.3 Installation 3.4 Operation 3.5 Breakdown 3.6 Decommissioning 3.7 Disposal	**3. Description of function**
4. List of standards applied	**4. Technical documentation** 4.1 Drawings 4.2 Descriptions 4.3 Standards 4.4 Results of the design calculations 4.5 Results of the examinations and test reports 4.6 Technical documentation for purchased parts 4.6.1 Declarations of conformity 4.6.2 Declarations of incorporation and assembly instructions	**4. List of standards applied**
5. Risk assessment 5.1 Description of the method employed 5.2 List of the essential health and safety requirements 5.3 Description of the protective measures performed 5.4 Description of the residual risk		**5. Hazard analysis** 5.1 List of hazards 5.2 Assessment of hazards 5.3 Protective measures 5.4 Residual risk

Content of documentation as per Machinery Dir.	Content of documentation as per Low Voltage Dir.	Content of documentation as per Press. Equipt. Dir.
6. Instructions 6.1 General description of the work equipment 6.2 Assembly 6.3 Installation 6.4 Operation and Maintenance 6.5 Breakdown 6.6 Decommissioning 6.7 Disposal		**6. Operating instructions with information on** 6.1 Mounting including assembly of different pieces of pressure equipment 6.2 Putting into service 6.3 Use 6.4 Maintenance, including checks 6.5 Technical details 6.6 If appropriate, indications of misuse
7. Technical file 7.1 Overall drawing of the machinery 7.2 Full detailed drawings 7.3 Drawings of control and power circuits 7.4 Technical documentation for purchased parts 7.4.1. Declarations of conformity 7.4.2. Declarations of incorporation and assembly instructions		**7. Technical documentation (depending on module!)** 7.1 General description of the pressure equipment 7.2 Conceptual design and manufacturing drawings and drawings of components, subassemblies and circuit diagrams 7.3 Descriptions and explanations necessary for an understnading of the said drawings and diagrams and the operation of the pressure equipment 7.4 Description of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied 7.5 Results of design calculations made, examinations carried out, etc. 7.6 Test reports
8. Test reports and certificates 8.1 In-house test reports 8.2 Third-party test reports		

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