

project data

Manufacturer		Original manufacturer: "Logo"
Manufacturer's address:		
Version of this complete document:		
Reason for change		
Date of last change: Designation of		
the machine: Machine type (model):		
Serial number/machine no.:		
year of commissioning		
Customer:		
address of the customer		
Order number:		
Languages)		
Conformity assessment procedure:		
notified body:		

Responsible:

	Surname	date / date	Signature / Signature
Made by / created by			
Checked by / verified by			
Approved by / released			
documentation officer			

project Manager

mechanical designer:	
Electrical designer:	
Designer control:	
Designer media:	

1. Purpose of the risk assessment

This documentation serves as proof of the directive-compliant planning/construction of the machine/system described under "Description of the machine/system".

Compliance with the basic health and safety requirements of the EC Machinery Directive 2006/42/EC is documented ~~and other relevant internal market directives.~~ This proof is part of the technical documentation in accordance with Annex VII of the EC Machinery Directive, does not fully reflect this.

The hazard analysis (identification of hazards) is part of the comprehensive **risk assessment according to DIN EN ISO 12100**. Based on the determined and assessed risks, appropriate risk reduction measures were defined after observing the relevant safety regulations.

The risk assessment and the protective measures implemented on the machine/system authorize according to Articles 5 and 12 of the EC Machinery Directive line 2006/42/EG for issuing the EC declaration of conformity and for affixing the CE mark. The entire machine can be used for this documentation can be completed with this.

2. Execution See [1] p.50
When conducting the risk assessment, the following guidelines and guidelines for the procedure were observed: **EG machines Annex I General principles Directive Annex I No. 1.1.2 Principles for the integration of safety 2006/42/EG Annex VII Technical**

- DIN EN ISO 12100** Machine safety –
General design principles - risk assessment and risk reduction
- DIN EN ISO 13849** Machine safety –
Safety-related parts of controls
Part 1: General design principles

A hazard checklist (see [p. 14 hazard checklist](#)) and action sheets (see [p. 26 action sheets](#)) were essential tools for implementation and documentation .

Hazard identification of hazards **checklist**

measures sheets	Risk assessment and description of protective measures
------------------------	--

This verification documentation also includes the documents used in the risk assessment

DIN ISO/TR 14121-2:2013-02	Risk assessment according to Section 6.5.2 Example of a hybrid of risk assessment tools or methods Risk assessments
Attachment 1	Control measures
Attachment 2	
Attachment 3	list of standards
...	

The hazards marked with a cross in the **hazard checklist** were identified for the designated machine/system (see [p. 20 hazard assessment and description](#))

The machine-specific details, risk assessments and protective measures taken to reduce risk are described in the action sheets as part of a safety and operating concept (see p . 28 **safety plan**).

The information in the hazard checklist (columns 3 to 8) and in the action sheets (column 9) serve in the sense of the EC Machinery Directive 2006/42/EC as a list of

- basic requirements of the Machinery Directive • standards

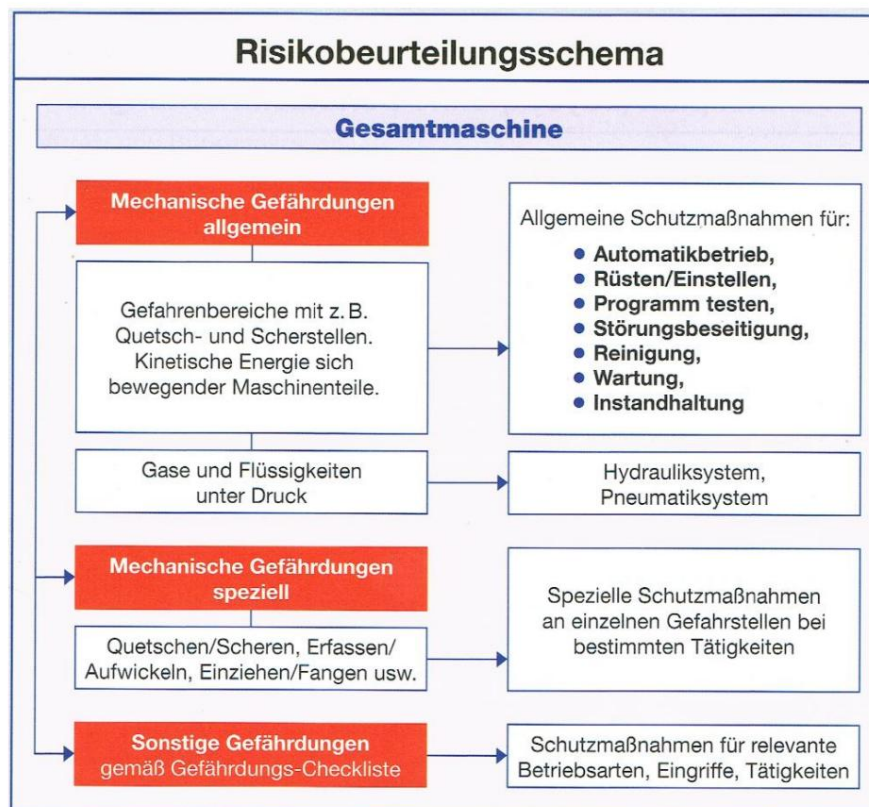
and the

- other technical specifications,

which were taken into account when designing the machine. The titles of the standards and other technical specifications are listed in the list of standards in this verification documentation and – where applicable – marked with a cross.

The required compliance with the basic requirements of all relevant internal market directives has been achieved. If this is not possible due to the state of the art, this will be indicated in the **action sheets** (column 9) (residual risk).

The following assessment scheme shows the basic procedure.



3. Description of the machine/plant

3.1. characteristics

Product:	"Machine" in the sense of the Machinery Directive 2006/42/EG Article 2 / point a
designation	
Manufacturer	
type designation	
machine no.	
Construction year	
Type/shape/weight of the workpieces	
quantity	
operating mode	
Location	
Space requirements (see installation plan)	
operating personnel	
Installer/Maintenance	
rated capacity	
Electrical connection	
Degree of protection	
pneumatic connection	
communication system	
Expected life of the asset	
Inspection/Maintenance/Cleaning	
Applicable Documents	

3.2. Intended use, limits of the machine Description

usage limits		related documents
Intended Use		
Foreseeable improper use (misuse/abuse)		

3.2.1. Spatial Boundaries

Movement space, space required by people who handle the machine, e.g. during operation and maintenance Interface(s): Human/energy supply Human/machine

Here is a general description, details are in the associated documents
floor plan

	associated documents/description
Description of the machine:	
Interfaces to other machines	
Interfaces to energy supply	
Interfaces for communication	
Overview drawing including parts list	
Requirements/specifications	
Technical description of performance	
Description of structure and components in the operating instructions Chap. xxx technical data in the operating instructions chap. xxx	

3.2.2. Temporal Boundaries

Limits of the service life of the machine / individual components, with intended use and foreseeable misuse Recommended maintenance intervals

Expected Machine Life	
Service life of wearing parts (list)	
Recommended maintenance intervals (list)	

3.2.3. More borders

Properties of the materials to be processed; required degree of cleanliness; minimum / maximum temperature in the environment / in the machine; Indoor/outdoor operation in dry/wet weather and in direct/indirect sunlight; Dust / moisture tolerant; Etc.

Materials being processed (list of hazards)	
Required degree of cleanliness Minimum/	
maximum temperature in the environment	
Minimum/maximum temperature in the machine	
Indoor/outdoor operation	
in dry/wet weather in direct/	
indirect sunlight	
Dust/wet tolerant	
Aggressive environmental conditions	
Etc.	

3.3. use

Environment of use	description		related documents
private			
Commercial, industrial use			
user groups	task	Qualification/Impairments	life stage
professional staff			
laymen			
trainee			
Children (specify age group)			
Elderly (no longer able to work)			
Disabled people (persons with limited mental and physical abilities)			

3.4. materials

materials	material	use	related documents
dangerous substances			
hazardous materials			
hazardous processed materials			

3.5. Life phases Life

phases of the machine/plant		Dangerous activities, interventions, situations	Group of people at risk
A Construction			
B	Transportation		
C	Assembly installation Installation		
Application/Use D to M			
D	Automatic mode		
E	semi-automatic operation		
F	Manual operation		
G	Setup/adjustment		
H	Program, Testing		
I	Eliminate disturbances in workflow		
J	Observing production processes		
K	Troubleshooting		
L	Cleaning, maintenance		

M	Maintenance		
N	Decommissioning		

3.6. Operating modes of the machine The following overview shows the operating modes: Operating mode (name)

Abbreviation Description (e.g. functionality)		
automatic mode	automobile	
Semi-automatic operation	semi-auto	
manual operation	hand	
jog mode	Tip	
setup mode	Set up	
...		
All	All	Applies to all operating modes described here
Independently	No	This phase of life has no mode of operation

The operating modes can be different for each machine (name, abbreviation, functionality).

The team decides whether it is necessary to record and evaluate the hazards and safety functions depending on the operating mode.

Variants for the documentation of the operating modes:

- 1. The recording and evaluation of the hazards / safety functions apply to all operating modes
- 2. A note is noted for each recorded and evaluated hazard/safety function

Selected variant for documentation: Variant 2.

3.7. Determination of applicable guidelines and standards

policy	Policy No	Applicable	
		Yes	no
Machinery Directive	2006/42/EC		
Applicable standards:			
Electromagnetic compatibility	2004/108/EC		
Applicable standards:			
Low Voltage Directive	2006/95/EC		
Applicable standards:			
Devices and protective systems for the intended use in potentially explosive atmospheres 94/9/EG			
Applicable standards:			
pressure devices	97/23/EC		
Applicable standards:			
Simple pressure vessels	87/404/EEC		
Applicable standards:			
outdoors	2000/14/EC		
Applicable standards:			
Environmentally friendly design of energy-using products (eco-design)	2005/32/EC		
Applicable standards:			
...			
Applicable standards:			

4. Identification of hazards

4.1. Explanations for the use of the hazard checklist In a risk assessment, possible hazards must be determined for all life phases of a machine/system. The still unsecured machine/system is assumed.

Exception: Safe old or new machines integrated in systems are considered in their already safe state. A risk assessment is only required for such machines with regard to the interfaces.

In the case of large machines and larger production plants, a risk assessment carried out for sub-machines or sub-areas improves the overview. It can make sense to analyze and document individual phases of life separately.

The checklist can therefore be used for an **entire** machine (single machine or complex system), a **sub** - machine (machine of a complex system) or for a **subarea** of a machine/system. Risk assessments for sub-machines or sub-areas do not replace the risk assessment for a machine/system as a whole, insofar as this is necessary for the interaction of assemblies.

"**Entire machine**" is ticked in the following checklist , ie in this case the hazard checklist is used to identify hazards for the entire processing module (complete system). The intended use shows that this processing module works together with others, but **no entirety of machines** within the meaning of the Machinery Directive should result. Therefore, each processing module must be safe on its own. When combining modules, only the interfaces need to be considered with an additional risk assessment.

Columns **1** to **11** of the hazard checklist are explained below:

Column	running hazard number
1 Column 2	Possible hazards, hazardous situations and hazardous events in accordance with Annex B of DIN EN ISO 12100. The list in Annex B has been supplemented with "Other hazards", which can be entered if necessary. In the case of mechanical hazards , a distinction is made between general and special hazards. The latter can occur at individual danger points during certain activities.
Column 3	EC Machinery Directive Annex I No. ..., with which agreement (conformity) must be established. Conformity is verified by appropriate measures are taken if the risk to the machine/system applies (see column 8).
Column 4	Further internal market directives are entered here, with which con formality must be established. Appropriate measures are taken to ensure conformity if the machine/system is at risk (see column 8).
Column 5	Number of the paragraph that deals with the passage in DIN EN ISO 12100. The descriptions are taken into account if this is stated in column 8 is marked as applicable.
Column 6	Applicable European standards (EN ...; pr EN ...) of type A and B and international standards (ISO). They are applied when applicable (see column 8).

Column 7	Applicable national standards and technical specifications (e.g. accident prevention regulations, DIN standards, VDE regulations, VDI guidelines) in case European standards are missing.
Column 8	Tick possible hazards. All life phases of the machine/system (see 3.5 life phases) must be taken into account.
column 9	The position numbers of the installation plan (see ____) can be entered here where a corresponding risk is expected.
Column 10	All life phases of the machine/system (see 3.5 life phases) are entered here, with those with a corresponding hazard is calculated.

4.2. Hazard Checklist

Manufacturer		Danger - checklist					Sheet 1 of 6			
		Machine or system-specific dangers					Clerk: Date:			
		Machine / plant:								
		Type:	Machine no.: Year of construction: Order no.:							
		Customer:	Country: Sub-machine: Section: Establish							
Overall machine:		conformity with: Applicable standards/technical specifications					Date:			
running Hazards, no. hazardous situations, hazardous events	Applicable further EG- EN ISO 12100 further EN- National Ref. Life Directives Norms									
1	2	MRL Appendix I	Rules Yes No	phase(s)						
3	4	5	6	7	8	9	10			
1	Mechanical hazards General mechanical hazards from: Machine parts, tools, workpieces, e.g.:					TRBS 2111 BGI 5049 VDI 2854		see below		
	a) Shape (sharp edges, corners, points, etc.)	1.3 1.3.4		6.2.2.1 6.2.2.2 6.2.3 a)						
	b) Arrangement of moving parts (hazardous areas with e.g. crushing and shearing points)	1.3 1.3.8		6.2.3 b) 6.2.6 6.2.10						
	c) mass and stability (potential energy of parts moving under the influence of gravity: objects falling / toppling over / sinking, overturning of the machine)	1.1.5 1.3 1.3.1 1.3.3 1.3.9		6.3.1 6.3.2 6.3.3 6.3.5.2 6.3.5.4	EN349 EN ISO 13857 11161	BGI 5123				
	d) Mass and speed (kinetic energy of parts in controlled or uncontrolled movement: contact with moving parts; objects flying away, e.g. workpieces, tools, chips, fragments, waste)	1.3 1.3.7 1.3.7 1.3.8 1.4.1		6.3.5.5 6.3.5.6 6.4.1 6.4.3 6.4 .4 6.4.5						
	e) insufficient mechanical strength (risk of breakage or bursting); fragments,	1.3 1.3.2 1.3.3 1.4.1								
	Accumulation of energy, eg f) elastic elements (springs); g) liquids and gases under pressure; Residual energy (e.g. hydraulic/ pneumatic systems) h) Negative pressure	1.5.3; 1.6.3 1.3.2; 1.5.3 Pressure vessel directive 1.6.3 87/404/EEC Equipment Directive 97/23/EC Observe all EC		6.2.5 6.2.10	EN982 EN 983	BGR 237				
Identify all hazards		directives		Observe all relevant standards			see layout see table			

Machine or system-specific hazards Serial. Hazards, no.				Hazard checklist						Sheet 2 of 6	
hazardous situations, hazardous events	Establish conformity with MRL further EG- EN ISO 12100 further EN- National Ref. Life Annex II Directives	phase(s)		Applicable standards/techn. Specifications	Applicable		9	10			
1	2	3	4	5	6	7	8	9	10		
<div>↓</div> <div>Special mechanical hazards at individual hazardous points during certain activities</div> <div>1.1 Danger of crushing</div>						TRBS 2111 BGI 5049		see below			
		1.3			EN 953 EN 999 EN1005-3 EN1088 EN574 EN1760 EN61496 EN ISO 11161	BGI 575 BGI 670 BGI 5123					
	1.2 Shearing Hazard	1.3									
	1.3 Cutting or cutting hazard	1.3									
	1.4 Entanglement or Entanglement Hazard	1.3									
	1.5 Danger of being drawn in or caught	1.3									
	1.6 Impact hazard	1.3									
	1.7 Puncture or puncture hazard	1.3									
	1.8 Friction or Abrasion Hazard	1.3									
	1.9 Danger from the ingress or spurting of liquids under high pressure, broken pressure hoses being thrown about	1.3.2	Pressure Equipment Directive 97/23/EC		EN 982 BGR 237						
2 Electrical hazards						TRBS 2131		see below			
2.1 Direct contact of people with live parts	1.5.1; 1.6.3	Low voltage RL 2006/95/EC	6.2.9 6.3.2 6.3.3.2 6.3.5.4 6.4.4 6.4.5	EN 60204-1 BGV A3 EN 50178 BGR 132							
2.2 Touching parts that have become live due to faults. 2.3 Approaching high-voltage parts	1.5.1										
	1.5.1; 1.6.3										
2.4 electrostatic processes	1.5.2										
2.5 thermal radiation or processes such as the ejection of melted particles or chemical processes in the event of short circuits, overloads, etc.	1.5.1; 1.5.5										
Identify all hazards		Observe all EC directives		Observe all relevant standards			see layout see table				

Machine or system-specific hazards Serial. Hazards, no. hazardous				Hazard checklist			Sheet 3 of 6		
1	situations, hazardous events	Establish conformity with : A further EG- EN ISO 12100 Appendix I Policies		Applicable standards/techn. Specifications further EN- National Ref. Life standards	Applicable MRL Rules Yes No	phase(s)			
		3	4				9	10	
3	Thermal hazards resulting in 3.1 burns and frostbite and other injuries through contact of persons with objects or materials at very high or low temperatures, through open flames or and also through radiation from heat sources	1.5.5	RL for gas appliances 93/68/EEC	6.2.4 b) 6.2.8 c) 6.3.2.7 6.3.3.2.1 6.3.4.5				see below	
3.2	Health damage due to hot or cold working environment Noise hazards resulting in	1.5.5							
			2003/10/EC "Phy. agents, noise"			LVArbSchV		see below	
4.1	hearing loss (deafness) and other physiological impairments (e.g. loss of balance, loss of attention)	1.4.1 1.5.8		6.2.2.2; 6.2.3c) 6.2.4c); 6.2.8 c) 6.3.1; 6.3.2.1 b) 6.3.2.5.1; 6.3.3.2.1 6.3.4.2; 6.4.3 6.4.5.1 b) and c)	EN ISO 11688 11690 15667 EN1299				
4.2	Disruption of voice communication, disruption of acoustic signals, etc.	1.4.1 1.5.8							
5	hazards from oscillations (vibration)		2002/44/EC vibrations			LVArbSchV		see below	
5.1	Use of hand-held tools with the Er result of nerve and vascular disorders	1.5.9		6.2.2.2; 6.2.3 c) 6.2.8 c); 6.3.3.2.1 6.3.4.3 6.4.5.1 c)	CR1030 Guideline EN1032	VDI 2057 VDI 2062 VDI 3831			
whole	body vibration, especially in connection with forced postures	1.1.8 1.5.9							
6	Radiation Hazards		2006/25/EG phy. impacts		EN 12198	LVArbSchV		see below	
6.1	Low frequency, radio frequency, microwave (electromagnetic fields) radiation. 6.2 Infrared, visible and ultraviolet light	1.5.10		6.2.2.2 6.2.3 c) 6.3.3.2.1 ; 6.3.4.5 6.4.5.1 c)		BGV B 11 BGR B 11			
		1.5.10							
6.3	X-rays and gamma rays	1.5.10				X-rayV			
6.4	Alpha rays, beta rays, electron or ion beams, neutron beams 6.5 Laser beams	1.5.10 1.5.11				Radiation Protection Ordinance			
		1.5.12			EN 60825	BGV B 2 BGI 832			
Identify all hazards		Observe all EC directives		Observe all relevant standards			see layout see table		

Machine or system-specific hazards Serial. Hazards, no. hazardous situations, hazardous events				Hazard checklist						Sheet 4 of 6
		Establish conformity with : MRL further EG- EN ISO phase(s)		Applicable standards/techn. Specifications 12100 further EN- National Ref. Life Annex I Directives		Applicable rules		Yes No.		
1	2	3	4	5	6 norms	7	8	9	10	
7 Hazards from materials and substances (and through its components) processed or used by machines		1.1 1.4.1		6.2.2.2 6.2.3 b) 6.2.3 c) 6.2.4 a) 6.2.4 b) 6.3.1 6.3.3.2.1 6.3.4.4 6.4.5.1 c); 6.4.5.1 g)		Danger substanceV		see below		
7.1 Dangers from contact with or inhalation of hazardous liquids, gases, mists, vapors and dusts (hazardous substances); lack of oxygen		1.1.3; 1.1.7 1.5.13 ; 1.6.5 1.5.6;			EN 626-1	VDI 2262				
7.2 Fire or Explosion Hazard		1.5.7 ExplProtection-RL 94/9/EG			EN1127-1 EN13478	TRBS 2152 BGR 104 VDI 2263 sheet 3				
7.3 biological or microbiological hazards (from viruses or bacteria)		1.1.3; 1.6.5, 2.1				BioStoffV BGR 143				
8 Dangers from neglecting ergonomic principles when designing the machine , such as dangers from 8.1 an unhealthy posture or excessive exertion				6.2.2.1 6.2.7; 6.2.8 6.2.11.8 6.3.2.1 6.3.3.2.1	EN614 EN1005			see below		
		1.1.5; 1.1.6 1.6.2; 1.6.4								
8.2 insufficient consideration of the anatomy of hand/arm or foot/leg		1.1.6 2.2 1.1.2d			EN614					
8.3 Provision of personal protective equipment (PPE) instead of technical protective measures						BGV A 8				
8.4 inappropriate local lighting; insufficient view of the workplace		1.1.4			EN1837					
8.5 mental overload or underload, stress		1.1.6								
8.6 Human error (e.g. circumventing protective devices, not wearing the necessary PPE or wearing PPE in violation of the ban, disregarding warnings		1.1.2c; 1.1.6 1.2.2; 1.2.5 1.5.4; 1.7				BetrSichV TRBS BGR 500				
8.7 improper construction, placement or Identification of Controls 8.8 Improper Construction or Placement of optical or acoustic signals		1.2.2 1.7.1			EN842, 894, 981, 61310					
9 hazards d. Operating environment of the machine (e.g. temperature, wind, snow, moisture, lightning)		1.1.2a 1.2.1; 1.5.16		6.2.6; 6.2.11.11 6.3.2.1; 6.4.5.1 b)						
Identify all hazards		Observe all EC directives		Observe all relevant standards			see layout see table			

Machine or system-specific hazards				Hazard checklist			Sheet 5 of 6		
running hazard	Hazards, no. hazardous situations, hazardous events	Make compliant with : MRL other EC Appendix I	guidelines 3	Applicable standards/techn. Specifications EN ISO 12100 other EN national standards Rules 7			Yes	Applicable Ref. phase(s)	Life No. 10
1	2		4	5	6		8th	9	
	10 combinations of hazards (Danger increase through the addition of risks)	1.1.2a							
	11 Unexpected start, unexpected Spinning / over-revving (accelerating) or any comparable malfunction due to: failure / malfunction	1.2		3.31	EN ISO 1037 EN ISO 11161 EN ISO 13849 EN ISO 13850 EN50178 EN 60204-1 EN61000 Part 6-1 to Part 6-4 EN62061			see below	
11.1	of the control / regulating circuit (see also serial no. 14)	1.2.1							
11.2	Restoration of the energy supply after an interruption (e.g. power failure and power recovery). (see also item 12) 11.3 external influences on electrical equipment	1.2.6 1.6.3		6.2.11.7.1 6.2.11.7.2					
	(e.g. line interference, electromagnetic radiation)	1.2.1 1.5.11	EMC Directive 2004/108/EC	6.2.11.1; 6.2.11.4: 6.3.2.5.2; 6.3.3.2.5; 6.3.5.2					
11.4	other external influences (gravity, wind, wet, lightning, etc.)	1.2.1			EN60529				
11.5	Hardware and Software Errors	1.2.1				BGI 852-4			
11.6	Operating errors (see also serial no. 8), eg unintentional switching on of the machine due to unsuitable command devices	1.1.6; 1.2.1 1.2.2; 1.2.3, 1.2.5, 1.7			EN614				
	12 Disturbance of the energy supply (thereby e.g Danger of failure of protective devices, parts flying off or falling, non-execution of stop commands, change of machine parameters);	1.2 1.2.6		3.31; 6.2.11.1 3.32; 6.2.10 3.33	see item 11				
	13 Inability to stop the machine under optimal conditions (normal stop – operational stop – emergency stop)	1.2; 1.2.1; 1.2.4;1.2.4.4 1.2.6; 1.3.5		6.2.11.1; 6.2.11.3 6.2.11.6; 6.2.11.8 & 9; 6.3.5.2	EN ISO 13850				
	14 Error in control / regulation circuit (e.g. due to operational stress, external influences, hardware or software defects, logic errors, uncontrolled changes to safety- relevant machine parameters, interference in the control signals with wireless controls)	1.2 1.2.1; 1.2.3, 1.2.4: 1.2.5, 1.6.3 Observe		6.2.11	see no. 11				
Identify all hazards		all EC directives		Observe all relevant standards			see layout see table		

Machine or system-specific hazards Serial. Hazards, no. hazardous				Hazard checklist						Sheet 6 of 6	
1	situations, hazardous events	Establish conformity with : A further EG- EN ISO 12100 Appendix I Policies		Applicable standards/techn. Specifications further EN- National Ref. Life standards Rules			Applicable MRL Yes No. phase(s)				
		3	4	5	6	7	8	9	10		
15	Danger of circumventing protective devices due to a lack of solutions for all operating states and necessary interventions in the machine, e.g. when setting up, checking programs (process monitoring), eliminating disruptions in the work process and troubleshooting, inspection, cleaning, maintenance, repair	1.1.2a+c 1.2.5 1.4; 1.4.1 1.6; 1.6.4		6.2.11.1 6.2.13 6.3.3.1	EN1088	BGI 575 BGI 670					
16	Assembly and disassembly work Hazards such as handling/transport of heavy components; incorrect assembly and connections; Test runs (see also serial no. 1c, 15,17,18 and 19)	1.1.5; 1.3.1; 1.3.3; 1.3.9 1.5.4		5.4; 6.4.1.3; 6.4.5.1 b) 4; 5.4; 6.2.6; 6.4.1.3; 6.4.5.1							
17	Dangers during cleaning/maintenance , eg due to maintenance work while the machine is running; unsafe access to points of intervention; lack of facilities for safe energy separation and discharge; Bypassing protective devices when troubleshooting; Remote maintenance (see also serial no. 1c, 15,16,18 and 19)	1.3.1; 1.3.7 1.3.9; 1.5.15 1.6; 1.6.3		5.4; 5.5.3.2; 6.2.11.9; 6.3.2.4; 3.3; 5.3.2c); 5.3.3 b) ; 5.4; 5.5.2.3.1a); 5.5.3.2; 6.2.8e); 6.2.10; 6.2.11.9; 6.2.11.10; 6.2.11.12; 6.3.2.4; 6.3.3.1; 6.3.5.4; 6.4.5.1b); 6.4.5.1e); 6.4.5.1 h)							
18	Slipping, tripping or falling of people during the assembly, operation, maintenance and dismantling of machines	1.5.15 1.6.2		Annex B 6.3.5.6	EN ISO 14122	BGV A 1 BGR A1					
19	Danger of entering a machine / plant to be shut off from the control panel, for example because the danger zones are unclear (especially with automatic start); Lack of escape routes, emergency call options and precautions for freeing and rescuing people.	1.2.2; 1.2.3 1.5.14		6.3.5.3	EN ISO 11161						
20	Insufficient user information (Signals, warning devices, operating instructions, etc.)	1.1.2; 1.1.5 1.3.1; 1.3.2 1.3.7; 1.5.4; 1.7		6.4	EN62079						
21	Other hazards (additional risks in individual cases for all life phases of a machine/system depending on their type and size as well as installation and usage conditions)	Appendix I	all relevant EC directives		all relevant machines nominal norms	all relevant national rules					
Identify all hazards		Observe all EC directives		Observe all relevant standards			see layout see table				

2	
3	

4.4. Other hazards with certain machines/plants

EX protection, robots, ...

5. Safety and operating concept The risks for the hazards identified with the help of the hazard checklist (see page 14ff) and described on pages 20 to 20 have already been assessed. Risk reduction measures must now be defined. Protective measures are selected as part of a security and operating concept.

The safety and operating concept consists of the points _____ until _____.

The following is explained:

- to point 5.1 (see pages _____)

Required protective measures (overview)

Consideration of all identified hazards as well as production and operating requirements in the safety and operating concept.

It is tabulated for all life phases of the machine/system whether protective measures are necessary according to the hazard checklist.

It is also specified which production and operating requirements must be taken into account when selecting and describing the protective measures in the measure sheets. This is intended to prevent tampering with protective devices.

- to point 5.2 (see pages _____)

Explanations for creating the action sheets Here it is

recorded how the action sheets are to be used and filled out. **The explanations were taken into account in this analysis.**

- to point 5.3 (see pages _____)

Measure sheets The

measure sheets (sheet 1 to _____) are used for the machine or system-specific risk assessment and description of protective measures for safety-relevant phases of life.

The following were taken into

account: • All identified hazards according to the hazard checklist. •

Risk assessment according to DIN ISO/TR 14121-2:2013-02 ab

section 6.5.2 and description of the hazards (see pages 20 to _____)

• Basic safety and health protection requirements of the EC Machinery

Directive according to column 3 of the hazard checklist for hazards

marked "applicable". • Requirements from other internal market

directives

Column 4 of the hazard checklist.

• Applicable standards/technical specifications according to column 5 to 7 of the hazard checklist.

• Necessary protective measures taking into account safety, production and operating requirements (see Pages _____)

• Necessary measures according to the functional description the sides _____.

- to item 5.4 (see pages ____)

Functionality of the secured system In

the course of the selection of protective measures in the measure sheets (pages ____ to ____), a description is given of how the secured system functions and is to be operated. The purpose of the description is to avoid selecting unsuitable protective measures. This ensures that the operator can carry out all necessary activities and interventions without unreasonable hindrances.

- to point 5.5 (see pages ____)

Safety plan The

protective measures described in the measure sheets (pages____) are assigned measure numbers. Their entry in the on ____ results in an overview of the protective measures specified for the machine/system (page ____). layout plan on page

5.1. Required protective measures (overview)

company XXXXXXX XXX		Required protective measures (overview)						Editor: Date:	
Consideration of all identified hazards as well as important production and operating requirements in the safety and operating concept.									
life stages of construction		Danger points: present location/area/ hazards: machine/system object A		Necessary protective measures		Yes No		Remarks	
	B Transportation								
	C Assembly / Installation								
	EN Automatic operation semi-automatic operation								
	FK All modes with manual Control (no automatic operation)								
	DK General operation of the machine / Attachment								
	LM cleaning, Maintenance, maintenance								
	N Decommissioning, dismantling,								
See life cycle table Hazards according to the hazard checklist				See action sheets for details					

5.2. Explanations for creating the action sheets

For all machine or system-specific hazards identified with the help of the hazard checklist, the associated risks must be assessed and risk reduction measures defined on the basis of a safety and operating concept.

The risk assessment and description of protective measures can be documented with the help of measure sheets (sheets 1 to X).

In the case of large machines and larger production plants, a risk assessment carried out for sub-machines or sub-areas improves the overview. It can make sense to analyze and document individual phases of life separately.

The action sheets can therefore be used for an **overall** machine (single machine or complex system), a **sub** - machine (machine of a complex system) or for a **sub-area** of a machine/system.

Risk assessments for sub-machines or sub-areas do not replace the risk assessment for a machine/system as a whole, insofar as this is necessary for the interaction of assemblies.

It is already described in 4.1 Explanations for the use of the hazard checklist that it must be a complete machine. I.e. the measure sheets 1 to ____ are used to document the risk assessment and description of protective measures for a complete system.

Columns 1 to 11 of the action sheets are explained below.

Column	running Numbers of the identified hazards from the hazard checklist.		
1	Identified hazards from the hazard checklist.		
Column	All hazardous points (named after location, area or object) at which identified hazards must be expected.		
2	Position numbers of the respective system components <i>(see floor plan page 52)</i> .		
Column 3	Column 4	Column 5	Precise information as to when and where the relevant hazard occurs (hazardous situation, hazardous activity, cause of the hazard).
Column 6	Specification of the life phase(s) of the machine/system in which the corresponding hazard occurs (see life phases on page 9)		
Column 7	General risk assessment taking into account DIN EN ISO 12100 "General design principles - risk assessment and risk reduction" (see risk assessment and description, page 20). Risk levels for the states before and after risk reduction (e.g. high/low) can be specified , which result from the risk graph contained in the table depending on risk factors.		
column 8	<p>The risk assessment for the machine control must be carried out in accordance with DIN EN ISO 13849-1. Alternatively, DIN EN 62061 can also be used for safety-related electrical, electronic and programmable electronic control systems.</p> <p>In the risk assessment according to DIN EN 13849-1, the required performance level (e.g. PLr=d) must be determined and entered in column 8 for each safety function required according to column 9 of the control to be designed. Explanations of the design and development process of a control system according to DIN EN ISO 13849-1 can be found in Annex ____ For safety-related electrical, electronic and programmable electronic control systems, the safety integrity level (e.g</p> <p>SIL=2) and entered in column 8. Explanations can be found in Annex ____.</p>		
Column 9	Formulated protection goals, description of protection measures, indication of residual risks and instructions for user information.		
Column 10	Action number for the security plan.		
Column 11	Space for test notes Appendix ____		

Manufacturer		Measures sheet Machine							Sheet 2 of X	
or system-specific risk assessment and description of protective measures										
From hazard checklist		danger point		Dangerous situation, life risk assessment			Protection goal / protection measure			test
running Hazards Location	area / item Hazardous activity, general phase no .	object	No cause of danger			for the steering	residual risk	dimensions ver		
(short text)							user information	no _		
1	2	3	4	5	6	7	8th	9	10	11

5.4. Functionality of the protected machine/system

Taking into account all the requirements and basic protective measures provided according to 5.1 Required protective measures (overview), the safety, production and operating functions described below are specified for the machine/system. The details for implementation are contained in the action sheets.

5.5. security plan

The risk assessment has shown that, based on the identified hazards and the assessed risks, risk reduction measures must be implemented. All risk reduction details are described in columns 9 and 10 of the action sheets. Each measure is provided with a measure number, which is entered in the safety plan.

The safety plan clarifies at which points or components of the machine/system risk reduction measures are required.

~~The machine/system was designed and built taking this risk assessment into account.~~ **All risk reduction measures have been implemented and checked according to the notes in column 11 of the action sheets .**

~~The conformity of the machine/system with the guidelines is certified in the EC declaration of conformity.~~

6.

Attachments Attachment 1 – Risk

assessment As part of a comprehensive risk assessment, a risk assessment and evaluation must be carried out for each identified hazard. This serves the purpose of selecting suitable risk reduction measures.

Assessment and evaluation criteria are contained in:

EN ISO 12100	General design principles – Risk assessment and risk reduction
EN ISO 13849-1	Safety-related parts of controls – Part 1: General design principles
EN 62061	Security of machines - Functional safety of safety-related electrical, electronic and programmable electronic control systems

The general assessment of risks according to DIN EN ISO 12100 can be carried out with the help of Table 1, taking into account four risk factors. The level of risk is determined using a matrix of class and extent.

The risk is all the higher, the greater the possible extent of damage and/or the frequency, avoidance and probability of damage occurring.

Table 2 contains indications for risk assessment and risk reduction measures. The higher the identified risk, the more carefully suitable protective measures must be selected.

The risk assessment for safety-related parts of controls can be carried out using the risk graphs on pages 32ff. This also determines their contribution to risk reduction. The required **performance level according to DIN EN ISO 13849-1** can be determined with Figure 1 on page 32.

The risk assessment for safety-related electrical, electronic and programmable electronic control systems can be carried out using the numerical evaluation, as in the assessment of hazards, and the matrix on page 35. This determines the contribution to risk reduction. With this, the required **safety integrity level according to DIN EN 62061** can be determined.

The design of the safety-related parts of controls can be found in DIN EN ISO 13849-1 or DIN EN 62061, depending on the application.

The validation (analysis and testing) of the intended safety function can be carried out according to DIN EN ISO 13849-2 or DIN EN 62061. The risk assessment should be limited to one of the two standards.

General assessment of risks in the event of possible personal injury, taking into account DIN EN ISO 12100. The mixed form of instruments was used according to the example of DIN ISO/TR 14121-2:2013-02 Section 6.5.2 with the following form.

Table 1: Risk assessment form

Product: _____
Issued by: _____
Date: _____

Document number.: _____

Document part no.: _____

black area = high risk
gray area = medium risk white
area = low risk

initial risk assessment: Yes

effects	extent Se	Class CI = (Fr+Pr+Av)					frequency Mrs	probability Pr	avoidance Av
		4	8-10	11-13	14-15	5-7			
Death, permanent loss of an eye or arm, reversible loss of fingers, reversible medical care, first aid	4						1 h 5 very high < 1 h to 24 h		
	3						5 high < 24 h to 2 w 4 medium		
	2 1						< 2 w to 1 a 3 low 2 negligible	5 4 3	5
								impossible	3
							< 1 a	2 possible 1 probable	1

ref No.	Type. vessel No.	Danger	se	Mrs	Pr	Av	class		
1									
2									
3									

Details (description of the accident scenario) of Ref. No.

1	
2	
3	

Possible risk reduction measures by the manufacturer of a machine

Measures 1 to 3 listed below have priority over measures 4 to 6 and 7 to 11. This applies in particular to high and medium risks. Measures 4 to 11 are not a substitute for possible measures according to 1 to 3.

Concrete risk reduction measures must be specified for each individual machine or system, taking into account all circumstances and safety regulations.

Table 2: Indications for risk-reducing measures

1. Safety concept for all life phases of the machine/plant and all necessary interventions by the operator set up serving staff	EN ISO 12100 6. Risk Mitigation 6.2 Inherently safe construction 6.3 Technical Protection Measures 6.4 User Information
2. Eliminate hazards or reduce risks through • lower-risk processes, • less hazardous substances and materials, • constructive measures , • suitable technical protective measures .	
3. Carry out additional protective measures	
4. Create understandable operating instructions with information about residual risks	
5. Attach hazard and safety notices to the machine/system	
6. Provide signals and warning systems	
7. Require personal protective equipment to be worn where appropriate	
8. Specify the use of qualified personnel	
9. Offer specific training measures	
10. Require staff training	
11. Recommend issuing operating instructions	

Determination of the performance level (PLr for safety-related parts of controls according to DIN EN ISO 13849-1

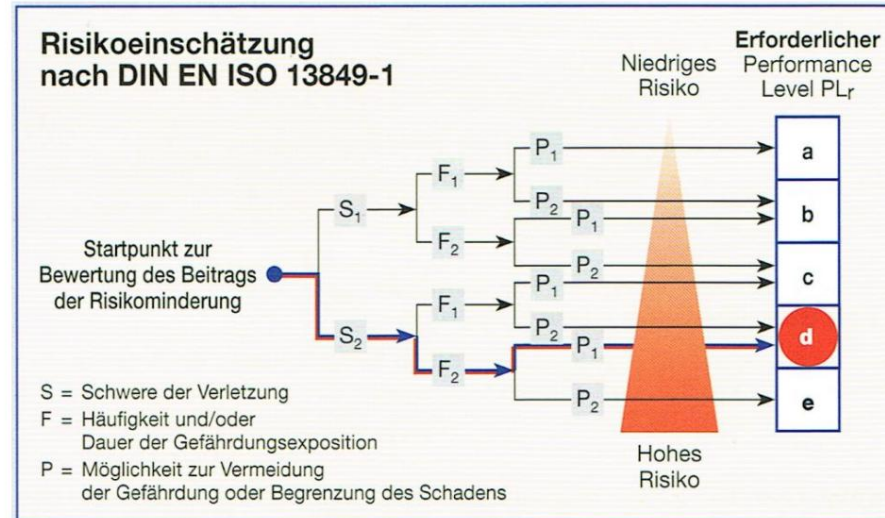


Figure 1: Determination of the required performance level PL_r.

The safety-related parts of a controller can include its hardware and software. According to the new European **standard DIN EN ISO 13849-1**, published in February 2007, with the risk parameters known from DIN EN 954-1, a control category no longer has to be determined **for each safety** function of a machine control, but a so-called **performance level (PL_r)**.

The performance level represents the ability of a safety-related part of a controller to carry out a safety function in order to achieve the required risk reduction, ie for the quality of the risk-reducing measures.

The performance levels are divided into **5 levels from a - e**. They reflect different residual risks - expressed in the probability of a dangerous failure per hour.

The individual **risk parameters (S, F and P)** have remained the same compared to the withdrawn DIN EN 954-1. For the example in Figure 1, the risk parameters S2, F2 and P1 result in a required performance level of PL_r = d.

The performance levels determined in this way for the individual safety functions can be achieved when designing a controller if, in addition to the previous controller categories, additional requirements, ie specific **reliability parameters**, are taken into account. DIN EN ISO 13849-1 contains further explanations.

Risk parameters according to DIN EN ISO 13849-1

(For selection information, see Appendix A of the standard)

S Schwere der Verletzung	F Häufigkeit und/oder Dauer der Gefährdungsexposition	P Möglichkeit zur Vermeidung der Gefährdung oder Begrenzung des Schadens
S1 leichte (üblicherweise reversible Verletzung)	F1 selten bis weniger häufig und/oder die Zeit der Gefährdungsexposition ist kurz	P1 möglich unter bestimmten Bedingungen
S2 ernste (üblicherweise irreversible Verletzung einschl. Tod)	F2 häufig bis dauernd und/oder die Zeit der Gefährdungsexposition ist lang	P2 kaum möglich

Figure 2: Risk parameters according to DIN EN 'so 13849-1

Unfortunately, the standard does not provide any information on what is to be understood by "reversible" and "irreversible injury". There is also no information on what is meant by "rarely to little" or what is meant by "frequently to constantly".

In practice, the approach has proven itself that reversible injuries are those that heal without long-term consequences. Examples include slight bruises and abrasions as well as first-degree burns.

In the recent past, what was rated as common was anything that happened more than once per shift or lasted more than an hour.

However, it turned out that these values may not be practical.

According to the current state of discussion, something that occurs at most once every 10 minutes should be rated as "rarely" or something that occurs more than 6 times an hour should be rated as "often".

Anything that lasts longer than an hour should be rated as "continuous".

However, a final statement from the responsible technical authorities is not yet available. Designers are therefore well advised if the "sharper pace" of the past can be used at reasonable cost. If this is not appropriate, the deviation must be justified.

Kategorien	Anforderungen (Kurzfassung)	Systemverhalten	Prinzip
B	Die sicherheitsbezogenen Teile von Steuerungen und/oder ihre Schutzrichtungen als auch ihre Bauteile müssen in Übereinstimmung mit den zutreffenden Normen so gestaltet, gebaut, ausgewählt, zusammengestellt und kombiniert werden, dass sie den zu erwartenden Einflüssen standhalten.	Das Auftreten eines Fehlers kann zum Verlust der Sicherheitsfunktion führen.	überwiegend durch die Auswahl von Bauteilen charakterisiert
1	Die Anforderungen von B müssen erfüllt sein. Bewährte Bauteile und bewährte Sicherheitsprinzipien müssen angewendet werden.	Das Auftreten eines Fehlers kann zum Verlust der Sicherheitsfunktion führen, aber die Wahrscheinlichkeit des Auftretens ist geringer als in Kategorie B.	
2	Die Anforderungen von B und die Verwendung bewährter Sicherheitsprinzipien müssen erfüllt sein. Die Sicherheitsfunktion muss in geeigneten Zeitabständen durch die Maschinensteuerung geprüft werden.	Das Auftreten eines Fehlers kann zum Verlust der Sicherheitsfunktion zwischen den Prüfungen führen. Der Verlust der Sicherheitsfunktion wird durch die Prüfung erkannt.	überwiegend durch die Struktur charakterisiert
3	Die Anforderungen von B und die Verwendung bewährter Sicherheitsprinzipien müssen erfüllt sein. Sicherheitsbezogene Teile müssen so gestaltet sein, dass 1. ein einzelner Fehler in jedem dieser Teile nicht zum Verlust der Sicherheitsfunktion führt und, 2. wann immer in angemessener Weise durchführbar, der einzelne Fehler erkannt wird.	Wenn der einzelne Fehler auftritt, bleibt die Sicherheitsfunktion immer erhalten. Einige, aber nicht alle Fehler werden erkannt. Eine Anhäufung unerkannter Fehler kann zum Verlust der Sicherheitsfunktion führen.	
4	Die Anforderungen von B und die Verwendung bewährter Sicherheitsprinzipien müssen erfüllt sein. Sicherheitsbezogene Teile müssen so gestaltet sein, dass 1. ein einzelner Fehler in jedem dieser Teile nicht zum Verlust der Sicherheitsfunktion führt und, 2. der einzelne Fehler bei oder vor der nächsten Anforderung an die Sicherheitsfunktion erkannt wird, oder, wenn dies nicht möglich ist, eine Anhäufung von Fehlern dann nicht zum Verlust der Sicherheitsfunktion führen darf.	Wenn Fehler auftreten, bleibt die Sicherheitsfunktion immer erhalten. Die Fehler werden rechtzeitig erkannt, um einen Verlust der Sicherheitsfunktion zu verhindern.	

Determination of the safety integrity level (SIL) for safety-related electrical, electronic and programmable electronic control systems in accordance with DIN EN 62061

The procedure is described in detail in Appendix A of DIN EN 62061. It is striking that it is very similar to the general risk assessment used here. It differs only in the matrix for evaluating the numerical assessments.

Table 3 below shows at the intersection of the row severity (S) with the applicable column (K) whether there is a need for action. The black-colored area shows the specified SIL as a target for the SRCF. The lighter shaded areas should be considered as a recommendation that other measures (AM) be applied.

Table 3: Matrix for determining the SIL

Severity (S)	Class (K)				
	4	5 to 7	8 to 10	11 to 13 14	to 15
4	SIL 2	SIL	SIL 2	SIL 3	SIL 3
3		(AT THE)	SIL	SIL 2	SIL 3
2			(AT THE)	SIL	SIL 2
1				(AT THE)	SIL 1

Using Table 3, this results in a one SIL assignment for the SRCF intended to mitigate the particular hazard.

Appendix 2 - Control Measures

company XXXXXXXXXX		control measures		Page 1 of 1
1. Safety checklist (effectiveness check) <p>Each selected risk reduction measure (here: column 9 in the measure sheets) must be evaluated in order to decide whether sufficient safety has been achieved or further risk reduction measures are required. Sufficient safety is only given if all questions on the safety checklist can be answered with "yes".</p>				
N	Safety Checklist	Yes	No	Comments
1	Have all the operating conditions and intervention procedures been taken into account?			
2	Were the protective measures selected according to the "3-step method"?			
3	Have all risks been eliminated or reduced to an acceptable level?			
4	Is it ensured that the measures taken do not create any new, unexpected hazards or problems?			
5	Are the users sufficiently informed about remaining residual risks?			
6	Do the measures taken allow easy handling of the Ma machine (user-friendly design)?			
7	Are all protective measures compatible with each other?			
8	Has the impact of non-commercial/non-industrial use of a machine designed for commercial/ industrial purposes been adequately considered?			
9	Is it ensured that the intended use of Ma machine is not impaired and there are no functional restrictions?			
<p>If one of the questions is answered with "No", further or different protective measures must be taken. If necessary, the entire safety and operating concept for the machine/system must be changed.</p> <p>If other risk reduction measures are selected, the process of risk assessment and evaluation must be carried out for any new risks that may arise. The selection of suitable protective measures and the risk assessment must be repeated until sufficient safety is achieved. Details on this are specified in DIN EN ISO 12100.</p>				
2. Tests (implementation control) <p>A check must be carried out on the finished machine/system to determine whether the selected protective measures are in place and effective. A separate test form or column 11 of the action sheets can be used as a checklist for this. The table shows a selection of possible tests.</p>				
Type of test	Test basis	Test of calculation documents	Calculations B test	abbreviation
before initial operation	Safety concept E	EG type examination	EN standards	EG test for electromagnetic compatibility
	Technical standards	EMC functional test (with or without workpiece)		
			Safety concept F	
Measurement of technical standards	M	Trial run (practical test under practical conditions)		
			Safety concept P	Visual
inspection of safety concept	S	Checking circuit diagrams (electrical/hydraulic/pneumatic diagrams)		
			Wiring diagrams	Sch Software
testing	Safety concept So	DIN EN ISO 13849-2 V Validation of safety-related parts of controls	Checkings/laying out documents	
material, stability test.)	Specialist standards	ZU	testing (e.g. pressure, load,	

Appendix 3 – List of

standards This list of standards contains standards and technical specifications that are listed in the hazard checklist. The specified EN standards are available as national DIN EN standards. The marked standards and technical specifications were used in the construction of this machine/ system (see hazard checklist columns 3 to 8 and action sheets column 9).

European and international standards (short title)		
Standards (EN, prEN, EN ISO, ISO)		applied
EN 349 Minimum distances EN 574		
Two-hand controls EN 614 Ergonomic design EN 60206		
Hazardous substances EN 842 Visual hazard signals EN 894		
Design of displays/controls EN 60335-1 EN 60335-2-109		
Visual and acoustic signals EN 1005-3 Human physical performance		
(force limits)		
CR 1030 Hand-Arm Vibration (Guide)		
EN 1032 Whole-body vibration EN 1037		
Avoidance of unexpected start protection EN 1127-1		
EN 1299 EN 1760 Pressure sensitive protective devices		
Pneumatics EN ISO 5554 Pneumatics EN 454 Systems EN		
ISO 11161 Integrated manufacturing systems EN ISO 12100		
EN ISO 11690 Low-noise workplaces General design principles		
- risk assessment and risk reduction EN 13478 Fire protection EN		
ISO 13849-1 Controls (design)		
EN ISO 13849-2 controls (validation)		
EN ISO 13850 Emergency stop EN ISO 13855		
Arrangement of protective devices with regard to the approach speed Safety distances Interlocking devices Noise protection		
EN ISO 13857 through silencers Stationary accesses Noise protection		
EN ISO 14119 encapsulation Electronic equipment Explosion protection		
EN ISO 14163 Electrical equipment Housing protection types Laser devices		
EN ISO 14122 Low-voltage switchgear Electromagnetic compatibility (EMC)		
EN 150 15667		
EN 50178 EN 60079 EN		
60204-1 EN		
60529 EN		
60825 EN		
60947 EN		
61000 Part 6-1 to 6-4 DIN		
EN 61241-14 Electrical equipment for use in areas with combustible dust		
Displays, license plates, operating elements Non-contact		
EN 61310 protective devices EI. programmable systems presence		
EN 61496 detection of people		
EN 61508		
EN 62046		

EN62061	Functional safety of controls	
BG regulations (BGV) - rules (BGR) - information (BGI)		applied
BGV A 1	Principles of Prevention	
BGV A 3	Electrical systems and equipment	
BGV A 8	safety marking	
BGV B 2	laser radiation	
BGV B 11	electromagnetic fields	
BGR 104	Explosion Protection Rules	
BGR 109	Grinding, brushing, polishing aluminum	
BGR 143	Activities with cooling lubricants	
BGR 237	hydraulic hose lines	
BGR 500	operation of work equipment	
BGI 575	Electromechanical locking devices	
BGI 670	Proximity switches in locking devices	
BGI 852-4	software	
BGI 5049	Security concepts and protective devices	
BGI 5123	industrial robot	
BGR 5127	Avoidance of ignition hazards due to electrostatic charging	
more rules		
BetrSichV	Ordinance on Industrial Safety and	
OStrV	Health Artificial optical radiation	
TRBS 2111	Mechanical hazards Hazards from	
TRBS 2121	falling Hazardous explosive	
TRBS 2152	atmosphere Ordinance on Hazardous Substances	
<small>Hazardous Substance Ordinance</small>	of 26 December 2010 Noise and Vibration Occupational	
LVArbSchV	Safety Ordinance Impact of mechanical vibrations Vibration	
VDI 2057	isolation Air quality at the workplace Dust fires and dust	
VDI 2062	explosions Dust separator Automated production systems	
VDI 2262	Pressure relief of dust explosions Mechanical vibrations	
VDI 2263	(protective measures)	
VDI 2264		
VDI 2854		
VDI 3673		
VDI 3831		

