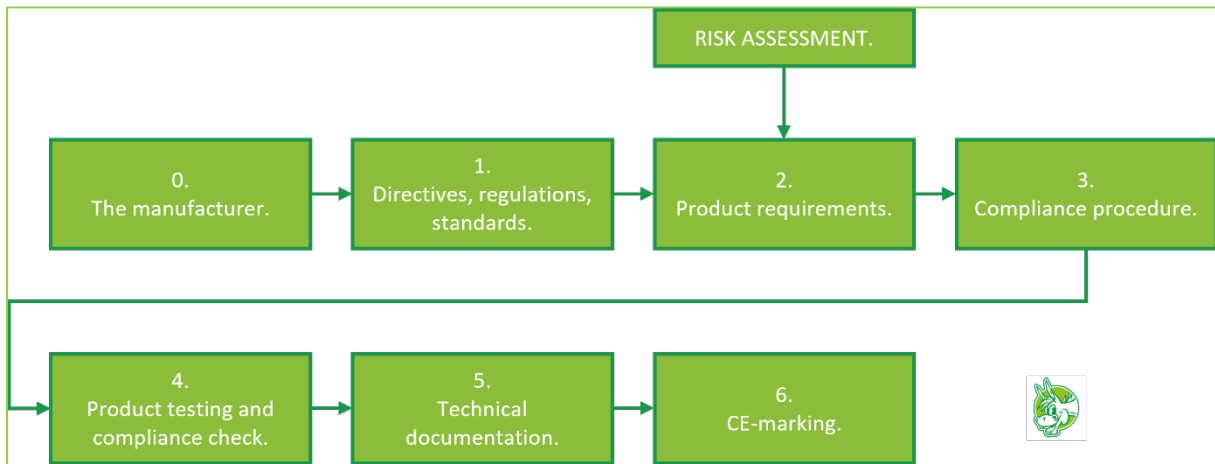


Purpose of this document

This is the user manual for the CE-assistant risk assessment tool.

Remember there also is a video tutorial. For this, you need to log in to your CE-assistant tool.

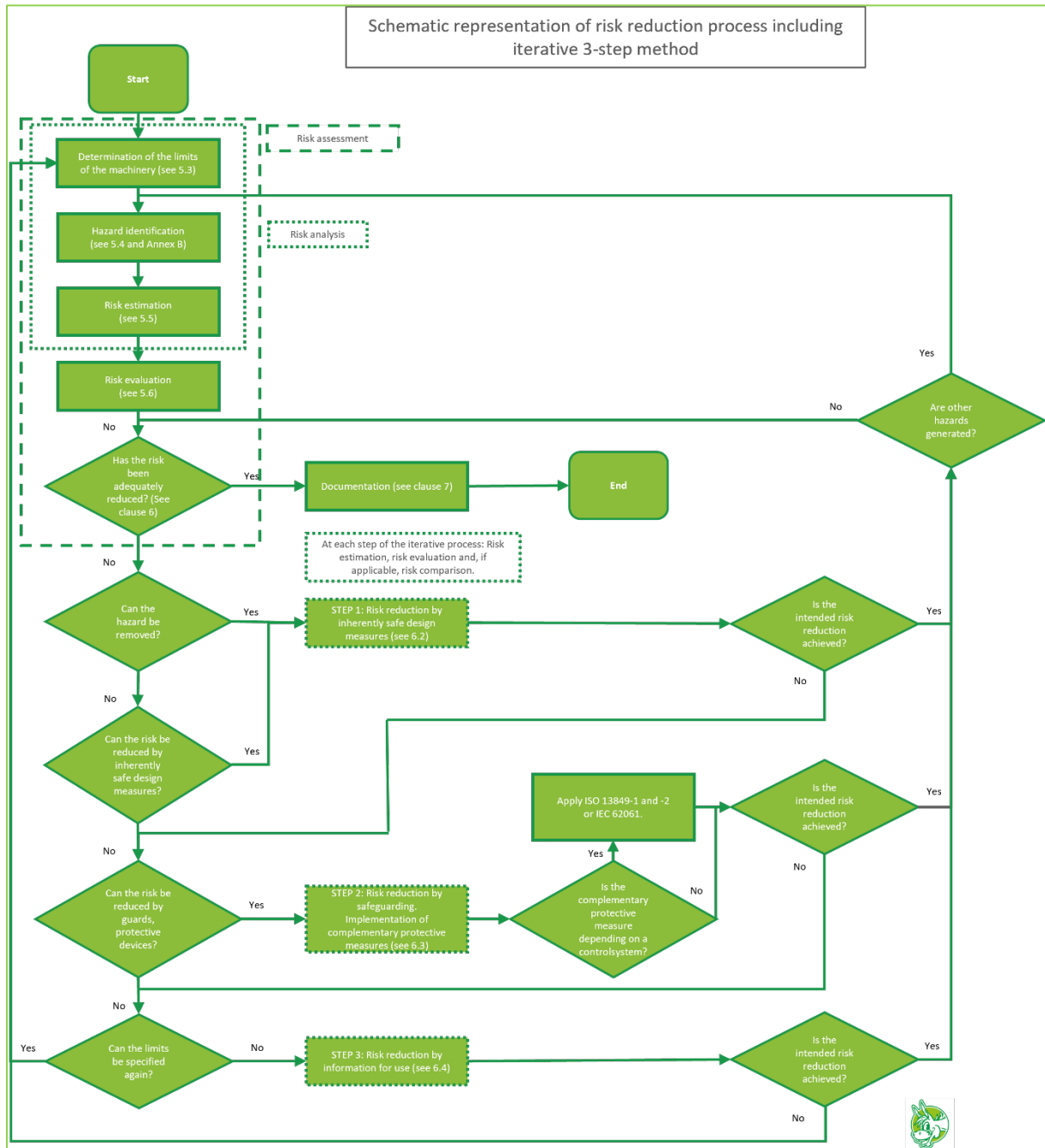
The risk assessment tool assists you with the obligated risk assessment during a CE-marking process as shown below. For more information about a CE-marking process please visit our website Homepage - ce-assistant.



This risk assessment tool is based on the a-standard EN-ISO 12100:2010.

The next figure shows the whole risk reduction process (based on ISO 12100's figure 1).

Schematic representation of risk reduction including iterative 3-step method



Worksheets in the risk assessment tool

The risk assessment tool consists of these sheets:

- **Start**, this introduction sheet displays the overall status of the risk assessment.
- **Manufacturer**, * this sheet displays machinery and manufacturer information.
- **Projectname&members**, * a sheet displaying the projectname and projectmembers.
- **..... limits**, * several sheets that display the limits of machinery as 5.3 of ISO 12100 dictates.
- **Informative**, this sheet informs you about the riskgraph method used in sheets 1→10.
- **1 Mechanical** → **10 Combination**: ISO 12100 divides possible hazards up into 10 hazardgroups. Each of these 10 sheets handles a hazardgroup. These sheets contain the actual risk assessment.

* The values and variables on these sheets can only be changed in the CE-assistant tool.

You do this in the projectscreen by pressing this button:

**View or change risk
assessment variables**

How this works is explained in the video tutorial, not in this user manual.

Sheets not marked * will be explained further on.

Who should fill out the risk assessment tool?

Risk assessments must be carried out carefully. This also applies to filling out the risk assessment tool. Assessing risks is a team effort. Some suggestions for team members:


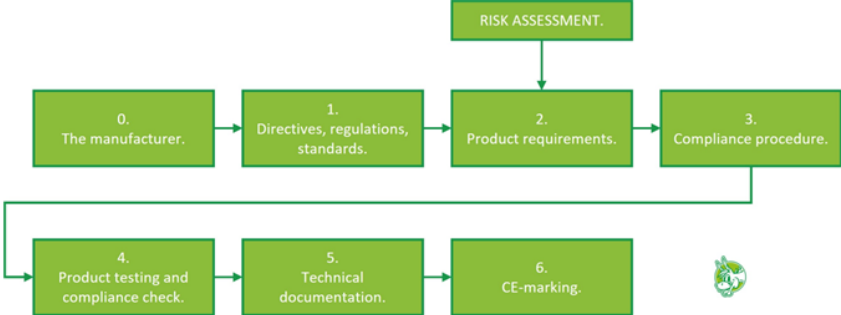
- Future user or someone with experience working with similar machines;
- Someone with knowledge of and influence on machine design;
- Service engineers;
- Cleaning staff;
- A coordinator who fills in the risk assessment tool effectively, ensures consensus and is familiar with the risk reduction process;
- Designing complex machinery? Enlarge your team with appropriate experts.

Sheets: Start

This is merely an informative sheet. It describes in short the sheets that are included in the risk assessment tool and the status of the risk assessment.

The risk assessment’s version is displayed top right.

There is nothing for you to fill in here:

A	B	C	D
1	What does this risk assessment tool do?		Version 2604
This risk assessment tool helps you to demonstrate your machinery is in compliance with EU legislation according to the CE-marking process as shown below. (More information about a CE-marking process wanted? See ce-assistant.com)			
When you are using the CE-assistant application there are manuals and video-tutorials available for this CE-roadmap. See the 'how it works' menu in the CE-assistant application.			
			
3			
4			

Here you can fill in the status of several sheets in the risk assessment tool:

Step	Sheet	Who will be the manufacturer?	Step completed?
0	Manufacturer	Manufacturer and machinery information: Can only be changed in the CE-assistant application	Yes
Step	Sheet	Projectname & members	Step completed?
R.A.	Projectname&members	Projectname: Can only be changed in the CE-assistant application	No
R.A.	Projectname&members	Projectmembers: Can only be changed in the CE-assistant application	Working on it
Step	Sheet	Applicable danger groups for this project	Status of step.
R.A.	1	Mechanical dangers	Applicable and finished
R.A.	2	Electrical dangers	Applicable, not finished
R.A.	3	Thermal dangers	Not applicable
R.A.	4	Noise dangers	Select value: <input type="text"/>
R.A.	5	Vibration dangers	Select value: <input type="text"/>
R.A.	6	Radiation dangers	Applicable, not finished
R.A.	7	Material-substance dangers	Applicable and finished
R.A.	8	Ergonomic dangers	Not applicable
R.A.	9	Environmental dangers	Select value: <input type="text"/>
R.A.	10	Combination of dangers	Select value: <input type="text"/>
Step	Sheets	Limits of machinery	Step completed?
R.A.	Use limits	Person involved / role	Yes
R.A.	Use limits	Use limits: Can only be changed in the CE-assistant application	Yes
R.A.	Space limits	Space limits: Can only be changed in the CE-assistant application	Yes
R.A.	Time limits	Time limits: Can only be changed in the CE-assistant application	Yes
R.A.	Other limits	Other limits: Can only be changed in the CE-assistant application	Yes

Remember that only sheets 1→10 can be directly filled in. Variables and values on all the other sheets can only be changed in your CE-assistant tool.

Sheets 1 Mechanical up to 10 Combination

These 10 sheets all work the same. Each sheet is named after a ISO 12100 hazard group. These groups are:

1. Mechanical
2. Electrical
3. Thermal
4. Noise
5. Vibration
6. Radiation
7. Material/substance
8. Ergonomic
9. Environmental
10. Combination

Group 1 is used for explaining.

Sheets 1 up to 10: Hazard identification

Hazards are identified in this part of the sheet:

Hazard identification									
	A	B	C	D	E	F	G	H	I
1									
2									
3									
4	Nr.	Hazard	Potential consequences	Remarks (free text)	Use limits	Space limits	Time limits	Other limits	
5	1								
6	2								
7	3								
8	4								
9	5								
10	6								
11	7								
12	8								
13	9								
14	10								

Nr.

In total there are 96 rows to use. You can not change these numbers.

Hazard

Based on the CE-roadmap format you have chosen in the CE-assistant tool, a dropdown box appears.

	A	B	C	D	E	F	G	H	I
1	Hazard identification								
2									
3									
4	Nr.	Hazard	Potential consequences	Remarks (free text)	Use limits	Space limits	Time limits	Other limits	
5	1								
6	2	ISO 12100-machinery mobility	<div style="border: 1px solid gray; padding: 2px;"> <ul style="list-style-type: none"> ISO 12100-moving elements ISO 12100-rotating elements ISO 12100-rough slippery surface ISO 12100-sharp edges ISO 12100-stored energy ISO 12100-vacuum. ISO 10218-2:2025-inappropriate selection of robot, robot safety functions ISO 10218-2:2025-inappropriate selection of end-effector, end-effector safety functions ISO 10218-2:2025-inappropriate selection of application machines, components and equipment and their safety functions ISO 10218-2:2025-inappropriate selection of robot application components, equipment and task programs ISO 10218-2:2025-end-effector design not suitable for the workpiece variability </div>						
7	3								
8	4								
9	5								
10	6								

Potential consequences

This is the actual risk you can assign to the hazard chosen in the same row. The dropdown box values are based on the CE-roadmap format you have chosen in the CE-assistant tool.

	A	B	C	D	E	F	G	H	I
1	Hazard identification								
2									
3									
4	Nr.	Hazard	Potential consequences	Remarks (free text)	Use limits	Space limits	Time limits	Other limits	
5	1								
6	2		<div style="border: 1px solid gray; padding: 2px;"> <ul style="list-style-type: none"> ISO 12100-shearing ISO 12100-slipping tripping and falling ISO 12100-stabbing or puncture ISO 12100-suffocation. ISO 10218-2:2025-crushing ISO 10218-2:2025-shearing ISO 10218-2:2025-cutting or severing ISO 10218-2:2025-entanglement ISO 10218-2:2025-drawing-in or trapping ISO 10218-2:2025-impact ISO 10218-2:2025-stabbing or puncture ISO 10218-2:2025-friction, abrasion </div>						
7	3								
8	4								
9	5								
10	6								
11	7								
12	8								
13	9								
14	10								

Remarks

The only free text cel in this part of the sheet. An example:

Hazard identification							
Nr.	Hazard	Potential consequences	Remarks (free text)	Use limits	Space limits	Time limits	Other limits
1	ISO 12100-kinetic energy	ISO 12100-impact	Depending on the workpiece's mass and handling speed when clamped.				

... Limits

These are all dropdown boxes. The values and variables in these boxes can only be changed in the CE-assistant tool. Here is an example.

Changing the use limits in the CE-assistant tool:

'Use limits' on sheet 'Use limits':

On the 'Use limits' sheet you will see the 'Use limits'.

There are no fixed values, please add or update use limits (for example auto mode, manual mode, cleaning mode, power off) here:

Results in this dropbox values:

Hazard identification							
Nr.	Hazard	Potential consequences	Remarks (free text)	Use limits	Space limits	Time limits	Other limits
1	ISO 12100-kinetic energy	ISO 12100-impact	Depending on the workpiece's mass and handling speed when clamped.				
2				Auto mode			
3				Manual mode			
4				Power off			
5				Cleaning mode			

For all other limits this works the same.

Determining limits can be difficult.

Remember that there is a standards viewer in your CE-assistant tool.

Project Standards

Here you find the standards that are mentioned in sheet '2.2c.2 10218-2 2025' of your CE-roadmap file!

EN-ISO 12100:2010
Safety of machinery - General principles for design - Risk assessment and risk reduction
12100 texts.pdf

ISO 12100:2010, amongst others, gives examples of limits.

Sheets 1 up to 10: Risk estimation and evaluation

The next step is estimating and evaluating the identified hazards without any measures taken. In this step the existing 'naked' risks are estimated and evaluates. It is only in the next step that, if necessary, measures are taken to lower these risks.

This is the part of the sheet where you can determine how risky the identified hazards really are. The roles (operator junior,.....) are entered in the CE-assistant tool's risk assessment variables screen.

Risk estimation and evaluation																													
Operator junior					Operator senior					Engineer					Programmer					Quality controller					Bystander				
S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R
				!					!					!					!							!			
				!					!					!					!							!			
				!					!					!					!							!			
				!					!					!					!							!			
				!					!					!					!							!			
				!					!					!					!							!			

To be filled in:

- S: Severity. A dropdown box.
- Fr: Frequency. A dropdown box.
- Pr: Probability. A dropdown box.
- Av: Avoidance. A dropdown box.
- R: Risk. A value resulting from S-Fr-Pr-Av.

The **Informative** sheet explains how risks are assessed:

The riskgraph method used in this risk assessment tool.

In sheet 1 up to 10 the values S, Fr, Pr and Av need to be filled in. The next figure offers assistance how to do this and shows which risk value (1 up to 14) is determined automatically.

Pay close attention to the underlined frequency remark. Not following this instruction results in the false risk value '!'.

S= Severity of the potential consequence

1

2

3

Fr= Frequency of exposure to the danger

1

2

1

2

Pr= Probability that the danger occurs

1 2 3

1	2	3	4	5	6
3	4	5	6	7	8
5	6	7	8	9	10
7	8	9	10	11	12
9	10	11	12	13	14

1 2 1 2 1 2

Av= Can the danger be avoided?

Severity

1= slight, reversible
2= serious, permanent
3= death

Frequency

0= Only & always when S=1
1= Seldom / sometimes
2= Often / mostly

Probability

1= low
2= medium
3= high



Avoidance

1= possible
2= impossible, hardly possible

Risk figure	Risk is	Measures
1 up to 4	Low	Risk is acceptable, ALARA
5 up to 7	Medium	Additional measures needed
8 up to 10	High	Immediate additional measures needed
11 up to 14	Very high	Stop work

Remember that risk figures also depend on the person involved/role. Meaning that the same hazards and potential consequences can have other risk figures for different roles. For example:

Operator junior					Operator senior				
S	Fr	Pr	Av	R	S	Fr	Pr	Av	R
1	0	1	2	2	2	2	1	1	5
2	2	2	1	7	2	2	2	2	8

When you do not use 9 persons involved/roles you can downsize the view by clicking . Expand the view again by clicking: 

Risk estimation and evaluation																													
Operator junior					Operator senior					Engineer					Programmer					Quality controller					Bystander				
S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R
				!					!					!					!					!					!
				!					!					!					!					!					!

Sheets 1 up to 10: Determination of PL and SIL

This can be used as an option and only by persons who know their way around Functional Safety and standards ISO 13849-1 & -2 and/or IEC 62061.

Functional Safety will not be explained here, but for those who are familiar with it, this is the part of the sheet to determine PL and SIL:

Determination of PL and SIL						
S	Fr	Pr	Av	SIL	PLr	
						-
						-

To be filled in:

- S: Severity. A dropdown box.
- Fr: Frequency. A dropdown box.
- Pr: Probability. A dropdown box.
- Av: Avoidance. A dropdown box.
- SIL & PLr: A value resulting from S-Fr-Pr-Av (see table A.6).

PL and SIL can be determined for potential consequences that result in functional safety risk reduction manners. It does not depend on several persons involved/roles, just assess the highest S-Fr-Pr and Av values as thinkable for the specific danger.

Remember that modern C-standards require specific SIL and PL values, ISO 10218-2: 2025 is an example of this.

Determining SIL and PL is based on IEC 62061: 2021's table A.6:

Table A.6 – Matrix assignment for determining the required SIL (or PL_r) for a safety function

Consequences	Severity Se	Class $CI = Fr + Pr + Av$													
		3	4	5	6	7	8	9	10	11	12	13	14	15	
Death, losing an eye or arm	4	SIL 1		SIL 2			SIL 2			SIL 3			SIL 3		
		PL _r b	PL _r c	PL _r d			PL _r d			PL _r e			PL _r e		
Permanent injury, losing fingers	3	No SIL (or PL) required		OM			SIL 1			SIL 2			SIL 3		
				PL _r a			PL _r b	PL _r c		PL _r d			PL _r e		
OM				SIL 1			SIL 2		SIL 1		SIL 2				
				PL _r a			PL _r b	PL _r c					PL _r d		
Reversible injury, medical attention	2	No SIL (or PL) required		OM			SIL 1			SIL 2		SIL 1		SIL 2	
PL _r a							PL _r b	PL _r c		PL _r d					
Reversible injury, first aid	1			OM			SIL 1			SIL 2		SIL 1		SIL 2	
							PL _r a			PL _r b	PL _r c				

A possible result:

Determination of PL and SIL						
S	Fr	Pr	Av	SIL	PL _r	
3	3	4	5	2	d	
2	5	2	3	OM	a	
4	4	5	5	3	e	

Sheets 1 up to 10: Risk reduction, new risk estimation and evaluation

Risks that are figured above 4 are too high and need to be reduced by taking measures. This certainly does not mean that taking measures to lower risk figured less than 4 is forbidden (it is admirable).

This is the part of the sheet where you read back the initial risk you filled in before, take measures if necessary and estimate and evaluate the risk after your measure(s).

Risk reduction, new risk estimation and evaluation							Risk reduction, new risk estimation and evaluation						
Operator junior							Operator senior						
R _{initial}	Risk reduction measure(free text)	S	Fr	Pr	Av	R _{new}	R _{initial}	Risk reduction measure(free text)	S	Fr	Pr	Av	R _{new}
2						1	5						1
7						1	8						1

Assessing potential consequences work the same as described before. The only difference is that ‘naked’ risks are not assessed but the remaining risks after reducing them.

As an example this can result in:

Risk reduction, new risk estimation and evaluation							Risk reduction, new risk estimation and evaluation						
Operator junior							Operator senior						
R _{initial}	Risk reduction measure(free text)	S	Fr	Pr	Av	R _{new}	R _{initial}	Risk reduction measure(free text)	S	Fr	Pr	Av	R _{new}
2	Speed reduction of tools when guards are open.	1	0	1	1	1	5	Speed reduction of tools when guards are open.	2	1	1	1	3
7	Only pendant control is possible inside the safeguarded zone	2	1	1	1	3	8	Only pendant control is possible inside the safeguarded zone	2	1	1	1	3

Sheets 1 up to 10: Residual risks

The last step of reducing risks (step 3) is risk reduction by information. When reduction implies a notice in the manual or a physical warning (for example a decal or warninglight), the use of PPE and more, you can mention this here. Also when you refer to a standard you can fill that one out here as a reminder to apply in your machinery design:

Residual risks			
Manual issue?	Warning issue?	Remark (free text)	Standard(s) to be applied
Select value:	Select value:		
Select value:	Select value:		
Select value:	Select value:		
Select value:	Select value:		
Select value:	Select value:		

To be filled in:

- Manual issue: A dropdown box.
- Warning issue: A dropdown box.
- Remark: Free text.
- Standard(s) to be applied: Free text.

A possible result:

Residual risks			
Manual issue?	Warning issue?	Remark (free text)	Standard(s) to be applied
Yes	Yes	Wearing of any hand-jewelry is not allowed.	
No	Select value:	When entering safeguarded zone a safety cap must be used.	
Select value:	Select value:		
Select value:	Yes		
Select value:	No		

When one or more risk figures are still too high go back to [‘Schematic representation of risk reduction including iterative 3-step method’](#).