



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 12100:2009**  
**01-junij-2009**

---

JUfbcghlfcYj !'Gd`cybUbU YU`bU flcj Ub`UžcWbU`h Y[ Ub`U]b`na Ub`yUb`Y  
h Y[ Ub`UfIGC#B -G`%&/\$\$.&\$- Ł

Safety of machinery - General principles for design, risk assessment and risk reduction  
(ISO/DIS 12100:2009)

Sicherheit von Maschinen - Allgemeine Gestaltungsleitsätze, Risikobewertung und  
Risikominderung (ISO/DIS 12100:2009)

Sécurité des machines - Principes généraux pour la conception, l'appréciation du risque  
et la réduction du risque (ISO/DIS 12100:2009)

**Ta slovenski standard je istoveten z: prEN ISO 12100**

---

**ICS:**

13.110

Varnost strojev

Safety of machinery

**oSIST prEN ISO 12100:2009**

**en,fr,de**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**DRAFT**  
**prEN ISO 12100**

February 2009

ICS 13.110

Will supersede EN ISO 12100-1:2003, EN ISO 12100-2:2003, EN ISO 14121-1:2007

English Version

**Safety of machinery - General principles for design, risk assessment and risk reduction (ISO/DIS 12100:2009)**

Sécurité des machines - Principes généraux pour la conception, l'appréciation du risque et la réduction du risque (ISO/DIS 12100:2009)

Sicherheit von Maschinen - Allgemeine Gestaltungsleitsätze, Risikobewertung und Risikominderung (ISO/DIS 12100:2009)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 114.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

**Warning** : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

## Contents

Page

Foreword.....	3
---------------	---

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN ISO 12100:2011

<https://standards.iteh.ai/catalog/standards/sist/d01f2e5d-cb28-48be-a422-f41f6fa24bfd/sist-en-iso-12100-2011>

## Foreword

This document (prEN ISO 12100:2009) has been prepared by Technical Committee ISO/TC 199 "Safety of machinery" in collaboration with Technical Committee CEN/TC 114 "Safety of machinery" the secretariat of which is held by DIN.

This document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 12100-1:2003, EN ISO 12100-2:2003, EN ISO 14121-1:2007.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

### Endorsement notice

The text of ISO/DIS 12100:2009 has been approved by CEN as a prEN ISO 12100:2009 without any modification.

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

SIST EN ISO 12100:2011

<https://standards.iteh.ai/catalog/standards/sist/d01f2e5d-cb28-48be-a422-f41f6fa24bfd/sist-en-iso-12100-2011>





## DRAFT INTERNATIONAL STANDARD ISO/DIS 12100

ISO/TC 199

Secretariat: DIN

Voting begins on:  
2009-02-26Voting terminates on:  
2009-07-26

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

## Safety of machinery — General principles for design, risk assessment and risk reduction

*Sécurité des machines — Principes généraux pour la conception, l'appréciation du risque et la réduction du risque*

(Revision of ISO 12100-1:2003, ISO 12100-2:2003 and ISO 14121-1:2007)

ICS 01.040.13; 13.110

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

### ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

**To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.**

**Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.**

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

## ISO/DIS 12100

**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

SIST EN ISO 12100:2011

<https://standards.iteh.ai/catalog/standards/sist/d01f2e5d-cb28-48be-a422-f41f6fa24bfd/sist-en-iso-12100-2011>

**Copyright notice**

This ISO document is a Draft International Standard and is copyright-protected by ISO. Except as permitted under the applicable laws of the user's country, neither this ISO draft nor any extract from it may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, photocopying, recording or otherwise, without prior written permission being secured.

Requests for permission to reproduce should be addressed to either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Reproduction may be subject to royalty payments or a licensing agreement.

Violators may be prosecuted.



# Contents

Page

Foreword .....	iv
Introduction.....	v
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	1
4 Strategy for risk assessment and risk reduction .....	8
5 Risk Assessment.....	12
5.1 General .....	12
5.2 Information for risk assessment.....	12
5.3 Determination of the limits of the machinery .....	13
5.4 Hazard identification .....	14
5.5 Risk estimation .....	16
5.6 Risk evaluation .....	21
6 Risk reduction.....	22
6.1 General .....	22
6.2 Inherently safe design measures.....	23
6.3 Safeguarding and complementary protective measures .....	33
6.4 Information for use.....	45
7 Documentation of risk assessment and risk reduction .....	49
Annex A (informative) Schematic representation of a machine.....	50
Annex B (informative) Examples of hazards, hazardous situations and hazardous events.....	51
Annex ZA (informative) Relationship between this International Standard and the Essential Requirements of EC Directive 2006/42/EC.....	61
Bibliography.....	62
Trilingual index of specific terms and expressions used in ISO 12100.....	65

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 12100 was prepared by Technical Committee ISO/TC 199, *Safety of machinery* and by Technical Committee CEN/TC 114, *Safety of machinery* in collaboration.

This second edition cancels and replaces ISO 12100-1:2003, ISO 12100-1:2003/Amd 1: 2009, ISO 12100-2:2003, ISO 12100-2:2003/Amd 1: 2009 and ISO 14121-1:2007 of which it constitutes a combination.

SIST EN ISO 12100:2011

<https://standards.iteh.ai/catalog/standards/sist/d01f2e5d-cb28-48be-a422-f41f6fa24bfd/sist-en-iso-12100-2011>

## Introduction

The primary purpose of this International Standard is to provide designers with an overall framework and guidance for decisions during the development of machinery to enable them to design machines that are safe for their intended use. It also provides a strategy for standard makers and will assist in the preparation of consistent and appropriate type-B and type-C standards.

The concept of safety of machinery considers the ability of a machine to perform its intended function(s) during its life where risk has been adequately reduced.

This International Standard is the basis for a set of standards which has the following structure:

- **Type-A standards** (basic safety standards) giving basic concepts, principles for design, and general aspects that can be applied to machinery;
- **Type-B standards** (generic safety standards) dealing with one safety aspect or one type of safeguards that can be used across a wide range of machinery:
  - type-B1 standards on particular safety aspects (for example safety distances, surface temperature, noise);
  - type-B2 standards on safeguards (for example two-hand controls, interlocking devices, pressure sensitive devices, guards);
- **Type-C standards** (machine safety standards) dealing with detailed safety requirements for a particular machine or group of machines.

This International Standard is a type-A standard.

When a type-C standard deviates from one or more technical provisions dealt with by this International Standard or by a type-B standard, the type-C standard takes precedence.

It is recommended that this International Standard be incorporated in training courses and manuals to convey basic terminology and general design methods to designers.

ISO/IEC Guide 51 has been taken into account as far as practicable at the time of drafting of this International Standard.

This International Standard gives in Annex B, in separate tables, examples of hazards, hazardous situations and hazardous events, in order to clarify these concepts and assist the designer in the process of hazard identification.

The practical use of a number of methods for each stage of risk assessment is described in ISO/TR 14121-2. This Technical Report, ISO/TR 14121-2, also gives some guidance on how the selection of protective measures (in accordance with this International Standard) can reduce the different elements of risk in relation to Figure 3 of this International Standard.



# Safety of machinery — General principles for design, risk assessment and risk reduction

## 1 Scope

This International Standard defines the basic terminology and specifies the methodology and principles for risk assessment and risk reduction to help designers in achieving safety in the design of machinery. These principles reflect the knowledge and experience of the design, use, incidents, accidents, and risks associated with machinery, and provide the basis for assessing and for the removal of hazards or the reduction of risks during the relevant phases of the life cycle of machinery.

This International Standard is also intended to be used as a basis for the preparation of type-B or type-C standards. The provisions stated in this International Standard are intended for the designer.

This International Standard does not deal with risk and/or damage to domestic animals, property or the environment.

This International Standard gives guidance on the information required to allow risk assessment to be carried out. Procedures are described for identifying hazards and estimating and evaluating risk.

This International Standard provides guidance for decisions to be made on the safety of machinery and guidance on the type of documentation required to verify the risk assessment and risk reduction carried out.

<https://standards.iteh.ai/catalog/standards/sist/d01f2e5d-cb28-48be-a422-f41f6fa24bfd/sist-en-iso-12100-2011>

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60204-1: 2005, *Safety of machinery – Electrical equipment of machines – Part 1: General requirements*.

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

### 3.1

#### **machinery**

#### **machine**

an assembly, fitted with or intended to be fitted with a drive system consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application.

NOTE 1 The term "machinery" also covers an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole.

NOTE 2 Annex A provides a general schematic representation of a machine.

## ISO/DIS 12100

**3.2****reliability (of a machine)**

ability of a machine or its components or equipment, to perform a required function under specified conditions and for a given period of time without failing

**3.3****maintainability (of a machine)**

ability of a machine to be maintained in a state which enables it to fulfil its function under conditions of intended use, or restored into such a state, the necessary actions (maintenance) being carried out according to specified practices and using specified means

**3.4****usability (of a machine)**

ability of a machine to be easily used thanks to, among others, properties or characteristics that enable its function(s) to be easily understood

**3.5****harm**

physical injury or damage to health

**3.6****hazard**

potential source of harm

NOTE 1 The term hazard can be qualified in order to define its origin (for example mechanical hazard, electrical hazard) or the nature of the potential harm (for example electric shock hazard, cutting hazard, toxic hazard, fire hazard).

NOTE 2 The hazard envisaged in this definition:

- either is permanently present during the intended use of the machine (for example motion of hazardous moving elements, electric arc during a welding phase, unhealthy posture, noise emission, high temperature);
- or may appear unexpectedly (for example explosion, crushing hazard as a consequence of an unintended / unexpected start-up, ejection as a consequence of a breakage, fall as a consequence of acceleration / deceleration).

**3.7****relevant hazard**

hazard which is identified as being present at or associated with the machine

NOTE 1 A relevant hazard is identified as the result of one step of the process described in Clause 5. It becomes a significant hazard when it is required to apply risk reduction measures.

**3.8****significant hazard**

hazard which has been identified as relevant and which requires specific action by the designer to eliminate or to reduce the risk according to the risk assessment

**3.9****hazardous event**

event that can cause harm

NOTE A hazardous event can occur over a short period of time or over an extended period of time.

**3.10****hazardous situation**

circumstance in which a person is exposed to at least one hazard

NOTE The exposure can immediately or over a period of time result in harm.

**3.11****hazard zone**

danger zone

any space within and/or around machinery in which a person can be exposed to a hazard

**3.12****risk**

combination of the probability of occurrence of harm and the severity of that harm

**3.13****residual risk**

risk remaining after protective measures have been taken

NOTE 1 This International Standard distinguishes:

- the residual risk after protective measures have been taken by the designer;
- the residual risk remaining after all protective measures have been implemented.

NOTE 2 See also Figure 2.

**3.14****risk assessment**

overall process comprising a risk analysis and a risk evaluation

**3.15****risk analysis**

combination of the specification of the limits of the machine, hazard identification and risk estimation

**3.16****risk estimation**

defining likely severity of harm and probability of its occurrence

**3.17****risk evaluation**

judgement, on the basis of risk analysis, of whether the risk reduction objectives have been achieved

**3.18****adequate risk reduction**

risk reduction at least in accordance with the legal requirements under consideration of the current state of the art

NOTE Criteria for determining when adequate risk reduction is achieved are given in 5.6.2.

**3.19****protective measure**

measure intended to achieve risk reduction, implemented:

- by the designer (inherently safe design, safeguarding and complementary protective measures, information for use) and/or
- by the user (organization: safe working procedures, supervision, permit-to-work systems; provision and use of additional safeguards; use of personal protective equipment; training).

NOTE See Figure 2.

**3.20****inherently safe design measure**

protective measure which either eliminates hazards or reduces the risks associated with hazards by changing the design or operating characteristics of the machine without the use of guards or protective devices

NOTE 6.2 deals with risk reduction by inherently safe design measures.

**3.21****safeguarding**

protective measure using safeguards to protect persons from the hazards which cannot reasonably be eliminated or risks which cannot be sufficiently reduced by inherently safe design measures

NOTE 6.3 deals with safeguarding.