

Masinate ohutus. Masinate konstrueerimisel kohaldatavad hügieeninõuded

Safety of machinery - Hygiene requirements for the design of machinery

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 14159:2008 sisaldab Euroopa standardi EN ISO 14159:2008 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 20.06.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 23.04.2008.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 14159:2008 consists of the English text of the European standard EN ISO 14159:2008.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 20.06.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 23.04.2008.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

ICS 13.110

Võtmesõnad:

Standardite reprodutseerimis- ja levitamisoigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:
Aru 10 Tallinn 10317 Eesti; www.evs.ee; Telefon: 605 5050; E-post: info@evs.ee

English Version

**Safety of machinery - Hygiene requirements for the design of
machinery (ISO 14159:2002)**

Sécurité des machines - Prescriptions relatives à l'hygiène
lors de la conception des machines (ISO 14159:2002)

This European Standard was approved by CEN on 21 March 2008.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists 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.



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of ISO 14159:2002 has been prepared by Technical Committee ISO/TC 199 "Safety of machinery" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14159:2008 by Technical Committee CEN/TC 114 "Safety of machinery" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2008, and conflicting national standards shall be withdrawn at the latest by October 2008.

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

This document supersedes EN ISO 14159:2004.

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 Directives.

For relationship with EC Directives, see informative Annex ZA and ZB which are integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: 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 the United Kingdom.

Endorsement notice

The text of ISO 14159:2002 has been approved by CEN as a EN ISO 14159:2008 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/37/EC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive Machinery 98/37/EC, amended by 98/79/EC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 98/37/EC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 98/37/EC, amended by 98/79/EC	Qualifying remarks/Notes
All clauses	Annex I, 2.1	Agri-foodstuffs machinery

WARNING — Other requirements and other EC Directives may be applicable to the product(s) falling within the scope of this standard.

Annex ZB (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 2006/42/EC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive Machinery 2006/42/EC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZB.1 — Correspondence between this European Standard and Directive 2006/42/EC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 2006/42/EC	Qualifying remarks/Notes
All clauses	Annex I, 2.1	Foodstuffs machinery etc.

WARNING — Other requirements and other EC Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Hazards	4
5 Hygiene requirements and/or measures	4
5.1 Strategy for selecting hygiene measures	4
5.2 Hygienic design	7
6 Verification of hygiene measures and test methods	11
7 Instruction handbook, maintenance and cleaning	11
7.1 Instruction handbook	11
7.2 Maintenance and cleaning	11
8 Additional information (limitations of use)	12
Annex A (informative) Categorization of machinery and associated equipment for intended use	13
Annex B (informative) Examples of good and bad hygienic design features	14
Annex C (informative) Relationship between International Standards referenced in clause 2 and corresponding European Standards	29
Bibliography	30

Introduction

This International Standard is one of a series of standards relating to the safety of machinery (ISO 12100 series). It differs from other safety standards, however, in that it is concerned with the associated hygiene risks of the machinery to the consumer of the product being processed, not to the operator of the machine.

Hygiene risks are very different from other safety risks. They are more associated with the ability of machines to be freed from product debris and micro-organisms, and thus preventing product contamination, rather than from the dangers of moving parts or electrical hazards to the operator. For this reason, and whilst this International Standard considers machines and their associated equipment, it can be used to provide guidance to the manufacturers of all equipment types where hygiene risks to the consumer of products to be processed by such equipment could occur.

This International Standard is a Type B standard (see ISO 12100) and as such is very general. It is applicable to all machines and associated equipment in applications where hygiene risks to the consumer of the product can occur (e.g., food, pharmaceuticals, biotechnology, cosmetics). Other standards, such as for example machinery specific Type C standards (see Bibliography), may be required to provide guidance for specific types of equipment and/or for specific industry sectors.

Historically, there have been cases where safety criteria have been addressed in machinery design without taking into account the implications linked to hygienic risks (and vice versa). In almost all cases, at least one of the different methods of design, safeguarding or residual safeguards can be chosen which will meet both safety and hygiene essential requirements and adequately control both risks. The option chosen shall satisfy both hygiene and safety risks, even if it may not be the most obvious option to have been adopted had the risk only been to safety or to hygiene.

When no design or safeguarding options are within the state of the art to adequately control both hygiene and safety risks, then one of the risks, or both, would have to be dealt with by residual safeguards, including instructions to the user. The assessment of the respective safety and hygiene risks shall indicate their relative significance, and the highest level of protection (i.e. safeguarding) shall be implemented to deal with the severest risk, and residual safeguards shall be used for the lesser risk.

The technical solutions given in this International Standard permit both objectives to be met for those significant and common risks identified as justifying common requirements specified in this International Standard.

Safety of machinery — Hygiene requirements for the design of machinery

1 Scope

This International Standard specifies hygiene requirements of machines and provides information for the intended use to be provided by the manufacturer. It applies to all types of machines and associated equipment used in applications where hygiene risks to the consumer of the product can occur.

This International Standard does not cover requirements relative to the uncontrolled egress of microbiological agents from the machine.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 4287:1997, *Geometrical Product Specifications (GP) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 12100-1:—¹⁾, *Safety of machinery — Basic concepts and general principles for design — Part 1: Basic terminology and methodology*

ISO 12100-2:—²⁾, *Safety of machinery — Basic concepts and general principles for design — Part 2: Technical principles*

3 Terms and definitions

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

3.1

associated equipment

all equipment associated with a machine, not defined as machinery (3.13), that is essential to the functioning of the machine for it to hygienically process a product (e.g. fittings, piping, tubing)

3.2

bond

joining of materials with an adhesive

1) To be published. (Revision of ISO/TR 12100-1:1992)

2) To be published. (Revision of ISO/TR 12100-2:1992)