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Safety of machinery — Hygiene requirements for the design of machinery

Sécurité des machines — Prescriptions relatives à l'hygiène lors de la conception des machines

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14159 was prepared by Technical Committee ISO/TC 199, *Safety of machinery*.

Annexes A to C are for information only.

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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.

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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)

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