FINAL
DRAFT

INTERNATIONAL STANDARD

ISO/FDIS 3533

ISO/PC **325**

Secretariat: SIS

Voting begins on:
2021-06-14

Voting terminates on:
2021-08-09

Sex toys — Design and safety requirements for products in direct contact with genitalia, the anus, or both

Sex toys — Exigences relatives à la conception et à la sécurité des produits destinés à être mis en contact direct avec les organes génitaux, l'anus ou les deux

Reference number
ISO/FDIS 3533:2021(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Project Committee ISO/PC 325 *Sex Toys – Design and safety requirements for products in direct contact with genitalia, the anus or both.*

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Sex toys are produced, marketed and sold in most countries in the world. These products are in touch with physically sensitive parts of the body. It may be embarrassing for the users to report issues concerning these products. Creating an international standard for sex toys regarding design, materials and user information would help both user, producers and re-sellers to make sure that the sex toys on the market are safe to use and that the user has enough information on how to use them correctly.

This document aims to ensure that the design of sex toys minimizes the risk of injuries to the user for reasonable and foreseeable use, that the materials are safe to use in contact with genitalia/anus or both, and also that there is sufficient and correct information provided to the user.

The requirements in this document are intended for manufacturers of sex toys. However, all parties in the supply chain may benefit from using this document as guidance.

Sex toys — Design and safety requirements for products in direct contact with genitalia, the anus, or both

1 Scope

This document specifies safety and user information requirements relating to the materials and design for manufactured products intended for sexual use.

This document covers only manufactured products that are intended to come in direct contact with genitals and/or the anus.

This document is not primarily intended for products classified as medical devices, cosmetics or assistive products for example lubricants, massage oil.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
sex toy
manufactured product intended for sexual stimulation or to enhance sexual pleasure

Note 1 to entry: Excluded: products classified as medical devices, cosmetics or assistive products; for example, lubricants, massage oil, intimate gels/sprays, and food supplements.

3.2
intended use
use for which a product is intended according to the specifications, instructions, and information provided by the *manufacturer* (3.4)[SOURCE: ISO 14971:2019, 3.6 — modified, process and service deleted, alternative term deleted].

3.3
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 51:2014, 3.9]

3.4
manufacturer
natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark

Note 1 to entry: Using a third party or subcontractor does not reduce the legal responsibilities of the manufacturer, nor does it move legal responsibilities to the third party or subcontractor.

Note 2 to entry: Importing a product constitutes the same legal responsibility as of a manufacturer.

3.5
sharp edge
accessible edge of a *sex toy* (3.1) which presents an unreasonable risk of injury during *intended use* (3.2) and reasonably foreseeable misuse

[SOURCE: ISO 8124-1:2018, 3.33 modified, sex toy, intended and misuse updated, hazardous deleted]

3.6
reasonably foreseeable misuse
use of a product in a way not intended by the *manufacturer* (3.4) but which can result from readily predictable human behaviour

Note 1 to entry: Reasonably foreseeable misuse can be intentional or unintentional.

[SOURCE: ISO 14971:2019, 3.15 modified, system deleted, note 1 to entry deleted]

3.7
foreseeable use
use of a product that is capable of being known or anticipated in advance based on a *manufacturer's* (3.4) best knowledge about the product

[SOURCE: ISO 10377:2013, 2.6 modified supplier's is changed to manufacturer's]

4 General requirements for risk management

4.1 General

The safety of the product shall be assessed based on a risk analysis identifying potential risks associated with the intended use of the product, from the design phase until disposal of the product.

The risk analysis process shall include:

— Risk assessment

— Documentation of the risk assessment

— Periodical review

— Post market control

Guidance on risk analysis is described in Annex A.

4.2 Risk analysis process

The manufacturer shall establish, document, and maintain throughout the lifecycle an ongoing process for identifying hazards associated with a sex toy, estimating, and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the risk controls in the post-market phase.

A risk management and analysis process can be part of the quality management system. This enables early detection of potential risks associated with the product, its intended use and reasonably foreseeable misuse.

4.3 Risk assessment

The manufacturer shall document any known or foreseeable hazards, or misuse associated with a sex toy. A risk estimation is performed for each hazardous situation identified. For each identified hazardous situation, the associated risk(s) shall be estimated using available information or data. For hazardous situations for which the probability of the occurrence of harm cannot be estimated, the possible consequences shall be listed for use in risk evaluation and risk control. The result of these activities shall be documented.

Each risk evaluation shall be reviewed periodically, based on user feedback, post-market surveillance and new scientific literature. Any modification or change to the product requires a new risk evaluation.

The manufacturer shall ensure that the person or team performing the risk assessment are competent to do so.

4.4 Post-market control

The manufacturer shall establish, document, and maintain a system to collect and periodically review information about the sex toy in the production and the post-market phases. This enables the manufacturer to conduct field corrective actions on individual production batches, if required.

Continuous assessment of product safety can be done via customer feedback. The data can be used to further improve the products, relating to, for example material and design safety.

5 Design requirements

5.1 General

All products shall be designed based on the intended use. As an integrated part of the design process, requirement specifications and risk assessment procedures shall be conducted to prevent any harm.

NOTE Design includes all aspects of the product including, shape, size, materials, packaging, and user information.

5.1.1 Anal use products

Products used on or in the anus, shall be designed so that the risk of retaining the product in the anal canal or rectum is minimized. They shall be designed with considerations based on the normal anatomy and physiology of the human anus and rectum. See Annex B for guidance.

If the product is inserted into the anus, methods of safely extracting it by the user is to be preferred over methods requiring medical expertise.

NOTE In case medical expertise is needed to extract retained objects or products, a common problem is that they cannot be grasped with fingers or instruments generally used for anal or rectal medical procedures.

5.2 Mechanical hazards

5.2.1 Prevention of retention

Manufacturers shall conduct a risk assessment, including considering anatomical design consideration described in Annex B, to find appropriate means of mitigation of the risk of retention the vagina, anus, rectum, or urethra. This shall be confirmed by using, as appropriate, references to relevant clinical and/or scientific literature in addition to requirements in this document.

5.2.1.1 Anal use products

A sex toy shall have sufficient mechanisms and design features to prevent them from being inserted further than intended to prevent retention in the anus or rectum during its intended use. The effectiveness of these design features shall be tested and documented. The flexibility of the product and the base-to-neck ratio should be considered.

EXAMPLE 1 Anal plugs, anal beads, anal dildos.

Medium and large products shall have design features making it possible for medical professionals to extract if retained, by using tools and instruments commonly used for medical procedures.

EXAMPLE 2 Loops, strings, or accessible edges.

5.2.1.2 Non-anal use products

Sex toys not intended for anal use, but which can be misused as such, shall have clear information in the user information of the intended purpose and how not to use the product.

Manufacturers should consider adding design features making retrieval possible for foreseeable anal retention.

5.2.2 Products for genital enclosure

A sex toy intended for enclosing genitals for example, penile rigidity ring, chastity devices, etc., shall be safely removable by the user. If genitals are trapped and the user unable to remove the device, the material strength (hardness) and the dimensions of the enclosing part shall allow safe removal with common household tools such as pliers. They shall not require the use of power tools for removal.

5.2.3 Moving and removable parts

If the product is designed with removable parts which may pose a risk when not properly fixed it shall have a locking mechanism which ensures that the parts stay in place during use and are only released when unlocked.

EXAMPLE Sex machine with replaceable dildos, battery compartments

5.3 Vibration

Hazards to the user from vibration shall be assessed in the risk analysis.

Manufacturers shall evaluate any vibration from powered sex toys in the intended environment(s) of use.

Mains powered products shall include an automatic time limit or clearly state maximum time of duration of use.

NOTE Manufacturers can consider standards relating to the effects of vibration, for example ISO 5349-1, ISO 5349-2, ISO 20643.

5.4 Electrical safety

The manufacturer shall consider the electrical safety of the product during the design phase, based on intended use and reasonably foreseeable misuse.

This includes the charger and charging of the product.

5.4.1 Electrical stimulation

Products intended to stimulate genitals via electric impulses shall be risk assessed by qualified third party and deemed safe to use.

NOTE A qualified third party can be a certified laboratory.

5.5 Surface temperature

For products with surface heating features, the risk analysis shall identify hazards and evaluate the risks associated with the surface temperature of parts which come into contact with the human body during the intended use.

The maximum surface temperature should not exceed 41 °C and shall never exceed 48 °C.

NOTE ISO 13732-1 states thresholds for burn.

The heating element shall be designed so it automatically turns off before the temperature of the surface exceeds 48 °C, taking into account temperature inertia.

The manufacturer should take into account a reasonable ambient temperature up to 30 °C and if the product is intended to be used internally or externally.

5.6 Design requirement for wireless remote-controlled products

For any remote-controlled product, the unit that is in touch with the body shall have a clear and simple way to turn it off.

5.7 Surfaces, corners, edges, and protruding parts

If not required for the intended function of the product, all accessible parts intended to be in contact with genitalia, the anus, or both shall be smooth and be free from burrs and sharp edges.

NOTE See ISO 8124-1:2018,4.6, 4.7, 5.8, 5.9, E.11 for information.

6 Materials

6.1 General

Manufacturers should consider environmental aspects of materials used and production methods without compromising the user’s safety.

6.2 Material safety

The manufacturer shall make sure that no chemicals in quantities known to be harmful for the user are used in the products.

The manufacturer shall establish a Restricted Substance List (RSL) including limits of substances that shall not be present in the materials that come into contact with mucosa.

The manufacturer should establish, implement, and maintain a procedure to identify the applicable laws and regulations of the countries where the products are manufactured, imported, distributed and sold, in order to ensure that applicable legal requirements are taken into account.

See Annex C for guidance on creating a Restricted Substance List.

All material safety information shall be made available during a procurement process.