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

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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.

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).

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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 standard 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.

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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

There are no normative references in this document.

3 Terms and definitions

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

3.1

sex toy

a 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

the use for which a product is intended according to the specifications, instructions, and information provided by the manufacturer.

[SOURCE: ISO 14971:2012, 2.5 modified]

3.3

risk

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

[SOURCE: ISO/IEC Guide 51:1999, 3.2]

3.4

manufacturer

a 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 which presents an unreasonable risk of injury during intended use 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 but which can result from readily predictable human behaviour.

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

[SOURCE: 14971:2019 ,3.15 modified]

3.7

foreseeable use

use of a product that is capable of being known or anticipated in advance based on a manufacturer's best knowledge about the product.

[SOURCE: ISO 10377:2013, 2.5 modified]

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. That 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.

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 or discomfort.

5.1.1 Anal use

Especially 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. 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 1 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.

NOTE 2 Objects which are not small enough to pass like stool often need surgical attention. Medium sized objects are usually too large to be passed naturally but can be removed if possible to grasp. Large objects are usually difficult to remove because the force required to extract them is considerable. A large object is also more likely to cause pressure ulceration and perforation of the bowel wall.

Table 1 — Product size classification

Product size classification			
	Small	Medium	Large
Length	≤ 4 cm	≤ 12 cm	> 12 cm
Diameter	≤ 2.5 cm at widest insertable point	≤ 3.5 cm at widest insertable point	> 3.5 cm at widest insertable point

The classification in [Table 1](#) is a general guide based on the normal anatomy and physiology of the human anus and rectum. See [Annex B](#) for more information.

5.2 Mechanical hazards

5.2.1 Retrieval and prevention of retaining

A sex toy shall have sufficient mechanisms and design to prevent retaining in the vagina, anus, or rectum during its intended use.

5.2.1.1 Anal use

Manufactures shall make a risk assessment, including considering anatomical design consideration described in [Annex B](#), to find appropriate means of mitigation of the risk of retention. This shall be

confirmed by using, as appropriate, references to relevant clinical and/or scientific literature in addition to requirements in this document.

Products for anal use shall have design features preventing them from being inserted further than intended.

EXAMPLE Anal plugs, anal beads, anal dildos.

Medium and large products shall have design features making it possible to extract if retained.

EXAMPLE Loops, strings, or accessible edges.

5.2.1.2 Non-anal use

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 (standards.iteh.ai)

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.

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.

EXAMPLE a qualified third party can be a certified laboratory.

5.5 Surface temperature

For products with surface heating feature 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.

If the product exceeds the limit it shall automatically turn off.

NOTE ISO 13732-1 states thresholds for burn.

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 clauses 4.6, 4.7, 5.8, 5.9, E.11 for information.

6 Materials

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6.1 General

Manufacturers should consider environmental aspects of materials used and production methods.

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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.

6.3 Biocompatibility

Sex toys are products with repeated contact with mucosa and possibly compromised tissue. Manufacturers shall make sure that the material of the products, that come into contact with mucosa, are biocompatible.