International Organization for Standardization
Organisation internationale de normalisation
Международная организация по стандартизации

Ch. de Blandonnet 8 | CP 401, 1214 Vernier | Geneva, Switzerland | T: +41 22 749 01 11 | central@iso.org | www.iso.org

Form 4: New Work Item Proposal

Circulation date: 2019-05-18 Closing date for voting: 2019-08-10	Reference number: NA (to be given by Central Secretariat)
Proposer (e.g. ISO member body or A liaison organization) SIS, Swedish Standards Institute	**ISO/TC** ☒ Proposal for a new PC
Secretariat SIS, Swedish Standards Institute	**N** Click here to enter text.

A proposal for a new work item within the scope of an existing committee shall be submitted to the secretariat of that committee with a copy to the Central Secretariat and, in the case of a subcommittee, a copy to the secretariat of the parent technical committee. Proposals not within the scope of an existing committee shall be submitted to the secretariat of the ISO Technical Management Board.

The proposer of a new work item may be a member body of ISO, the secretariat itself, another technical committee or subcommittee, an organization in liaison, the Technical Management Board or one of the advisory groups, or the Secretary-General.

The proposal will be circulated to the P-members of the technical committee or subcommittee for voting, and to the O-members for information.

IMPORTANT NOTE: Proposals without adequate justification risk rejection or referral to originator.
Guidelines for proposing and justifying a new work item are contained **in Annex C of the ISO/IEC Directives, Part 1.**

☒ The proposer has considered the guidance given in the Annex C during the preparation of the NP.

Proposal (to be completed by the proposer)

Title of the proposed deliverable.

English title:

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

French title (if available):

Click here to enter text.

(In the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

Scope of the proposed deliverable.

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

This document covers only 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 or assistive products.

Purpose and justification of the proposal*

Click here to enter text.

In a study published 2018 [1] Swedish researchers could see an increase in incidences of objects used for sexual pleasure retained in anus/rectum leading to severe surgical procedures. This finding was also supported by a systematic review based on available data which showed that the cases where patients require surgical extractions has increased across the world. This due the fact that objects used in the anus/rectum where not possible to remove the “natural way”. 40 percent of these objects where noted to be sex toys. However, the authors also suggested that the true figure of sex toy retention is likely even higher than the study suggests, given reluctance to seek care for a potentially embarrassing condition.

Sex toys are being produced, designed and sold globally, it is a global market with consumers across the globe. As there currently are no international standards or regulations specifically for these types of products, each manufacturer and retailer are free to make up their own test method and quality systems, at times based on standards and rules from documents with similar material or safety perspective, but not specific to the intended use of the actual product.

This proposed global standard intended for manufacturers, retailers, medical providers and consumers hopes to reduce incidences where sex toys do to misuse, or accidents cause unnecessary pain for users, save money for the health care sector and enables companies to show conformity. This by stating clear requirements for risk assessment, sufficient user information, outlining safety and quality requirements and providing recommended design considerations.

[1] Dahlberg, M., Nordberg, M., Pieniowski, E. et al. Int J Colorectal Dis (2019) 34: 181. https://doi.org/10.1007/s00384-018-3125-4

Consider the following: Is there a verified market need for the proposal? What problem does this standard solve? What value will the document bring to end-users? See Annex C of the ISO/IEC Directives part 1 for more information.

See the following guidance on justification statements on ISO Connect: https://connect.iso.org/pages/viewpage.action?pageId=27590861

Please select any UN Sustainable Development Goals (SDGs) that this deliverable will support. For more information on SDGs, please visit our website at www.iso.org/SDGs ."

☐ GOAL 1: No Poverty

☐ GOAL 2: Zero Hunger

☒ GOAL 3: Good Health and Well-being

☐ GOAL 4: Quality Education

☐ GOAL 5: Gender Equality

☐ GOAL 6: Clean Water and Sanitation

☐ GOAL 7: Affordable and Clean Energy

☐ GOAL 8: Decent Work and Economic Growth

☒ GOAL 9: Industry, Innovation and Infrastructure

☐ GOAL 10: Reduced Inequality

☐ GOAL 11: Sustainable Cities and Communities

☐ GOAL 12: Responsible Consumption and Production

☐ GOAL 13: Climate Action

☐ GOAL 14: Life Below Water

☐ GOAL 15: Life on Land

☐ GOAL 16: Peace and Justice Strong Institutions

N/A GOAL 17: Partnerships to achieve the Goal

Preparatory work (at a minimum an outline should be included with the proposal)

☒ A draft is attached ☐ An outline is attached ☐ An existing document to serve as initial basis

The proposer or the proposer's organization is prepared to undertake the preparatory work required:

☒ Yes ☐ No

If a draft is attached to this proposal,:

Please select from one of the following options (note that if no option is selected, the default will be the first option):

☐ Draft document will be registered as new project in the committee's work programme (stage 20.00)

☒ Draft document can be registered as a Working Draft (WD – stage 20.20)

☐ Draft document can be registered as a Committee Draft (CD – stage 30.00)

☐ Draft document can be registered as a Draft International Standard (DIS – stage 40.00)

☐ If the attached document is copyrighted or includes copyrighted content, the proposer confirms that copyright permission has been granted for ISO to use this content in compliance with clause 2.13 of the ISO/IEC Directives, Part 1 (see also the Declaration on copyright).

Is this a Management Systems Standard (MSS)?

☐ Yes ☒ No

NOTE: if Yes, the NP along with the Justification study (see Annex SL of the Consolidated ISO Supplement) must be sent to the MSS Task Force secretariat (tmb@iso.org) for approval before the NP ballot can be launched.

Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal.

☒ International Standard ☐ Technical Specification

☐ Publicly Available Specification

Proposed development track

☐ 18 months* ☐ 24 months ☒ 36 months ☐ 48 months

Note: Good project management is essential to meeting deadlines. A committee may be granted only one extension of up to 9 months for the total project duration (to be approved by the ISO/TMB).

***DIS ballot must be successfully completed within 13 months of the project's registration in order to be eligible for the direct publication process**

Draft project plan (as discussed with committee leadership)

Proposed date for first meeting: 2019-09-02 Stockholm

Dates for key milestones: DIS submission 2021-07-02

Publication 2022-07-02

Known patented items (see ISO/IEC Directives, Part 1 for important guidance)

☐ Yes ☒ No

If "Yes", provide full information as annex

Co-ordination of work: To the best of your knowledge, has this or a similar proposal been submitted to another standards development organization?

☐ Yes ☒ No

If "Yes", please specify which one(s):

Click here to enter text.

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables. The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized.

The proposal is specific to sex toys products which are not covered by regulation on medical devices or marketed as assistive products. There is no existing work for these products.

A listing of relevant existing documents at the international, regional and national levels.

Click here to enter text.

Please fill out the relevant parts of the table below to identify relevant affected stakeholder categories and how they will each benefit from or be impacted by the proposed deliverable(s).

	Benefits/impacts	**Examples of organizations/companies to be contacted**
Industry and commerce – large industry	Click here to enter text.	Click here to enter text.
Industry and commerce – SMEs	The proposed standard will give serious producers and retailers a tool to show conformity with a standard specific for their product, which may provide sales arguments and advantage in procurement.	Retailers, producers
Government	Many countries lack regulations of sex toys, this proposed standard can help authorities to regulate and increase quality for consumers. Reduced incidents will reduce cost for the public and private health care systems.	Consumer authorities
Consumers	The proposed standard will benefit consumers as it will be a useful tool for them to ensure the products have gone through a risk analysis and potential risks are mitigated.	Click here to enter text.
Labour	Click here to enter text.	Click here to enter text.
Academic and research bodies	Increased discussion and attention based on the work with this standard may lead to more research on the use of sex toys around the world. Today the research is very limited.	Click here to enter text.
Standards application businesses	Click here to enter text.	Click here to enter text.
Non-governmental organizations	Click here to enter text.	Click here to enter text.
Other (please specify)	Click here to enter text.	Click here to enter text.

Liaisons: A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable(s). Liaison with ISO/TC 157 *Non-systemic contraceptives and STI barrier prophylactics*	**Joint/parallel work:** **Possible joint/parallel work with:** ☐ IEC (please specify committee ID) Click here to enter text. ☐ CEN (please specify committee ID) Click here to enter text. ☐ Other (please specify) Click here to enter text.
A listing of relevant countries which are not already P-members of the committee. Note: The committee secretary shall distribute this NP to the countries listed above to see if they wish to participate in this work	
Proposed Project Leader (name and e-mail address) Johan Arrhenius, ja@ticklervibes.com Click here to enter text.	**Name of the Proposer** (include contact information) Anna Sjögren, SIS, Swedish Standards Institute. Anna.sjogren@sis.se
This proposal will be developed by: ☐ An existing Working Group (please specify which one: Click here to enter text.) ☐ A new Working Group (title: Click here to enter text.) (Note: establishment of a new WG must be approved by committee resolution) ☐ The TC/SC directly ☒ To be determined	
Supplementary information relating to the proposal ☒ This proposal relates to a new ISO document; ☐ This proposal relates to the adoption as an active project of an item currently registered as a Preliminary Work Item; ☐ This proposal relates to the re-establishment of a cancelled project as an active project. Other: Click here to enter text.	

Maintenance agencies and registration authorities

☐ This proposal requires the service of a **maintenance agency**. If yes, please identify the potential candidate:
Click here to enter text.

☐ This proposal requires the service of a **registration authority**. If yes, please identify the potential candidate:
Click here to enter text.

NOTE: Selection and appointment of the MA or RA is subject to the procedure outlined in the ISO/IEC Directives, Annex G and Annex H, and the RA policy in the ISO Supplement, Annex SN.

☒ Annex(es) are included with this proposal (give details)

The draft

Additional information/questions

Click here to enter text.