



## ISO/TC 338 MENSTRUAL PRODUCTS STRATEGIC BUSINESS PLAN

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### Executive summary

The strategic business plan for ISO/TC 338 Menstrual Products outlines the need for international standards in the menstrual product industry. The document emphasizes the importance of aligning ISO's work with business environment needs and trends, ensuring prioritization and adequate resources for projects.

The business environment of the ISO/TC 338 is characterized by the importance of menstrual health and the need for products that support physical, mental, and social well-being. It is described in terms of qualitative and quantitative factors. Qualitatively, the focus is on achieving menstrual health for women, girls, and all people who menstruate. Quantitatively, the document presents demographic considerations, market size, distribution, and pressures on margins. Menstrual products play a crucial role in allowing individuals who menstruate to participate fully in society. However, for countries where standards exist, there is a lack of harmonized international standards for menstrual products, which can hinder their availability and safety for countries where standards do not exist.

The market for menstrual products is significant, with 300 million people menstruating daily. The market size is projected to reach USD 33.1 billion by 2030, driven by both mature and growth markets. The demand for environmentally sustainable products and the emergence of reusable alternatives also impact the industry. However, the industry faces challenges such as margin pressures, distribution costs, import dependence, and high competition.

The establishment of international standards for menstrual products can address these challenges by ensuring product safety, quality, and performance while promoting innovation and sustainability. Standards for menstrual products can also contribute to achieving various Sustainable Development Goals related to no poverty, health and well-being, quality education, gender equality, clean water and sanitation, reduced inequalities, and responsible consumption and production.

In conclusion, the strategic business plan highlights the need for international standards in the menstrual product industry to improve access, ensure safety, quality, and performance.

## 1 Introduction

### 1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

### 1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: [ISO](#) (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of [IEC](#) (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of [ITU](#) (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 167 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the [International Standard](#).

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its [Technical Committees](#) are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

## 2 Business Environment of the ISO/TC

### 2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this ISO/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

Menstrual health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity, in relation to the menstrual cycle. As per the globally accepted definition of menstrual health, achieving menstrual health implies that women, girls, and all people who menstruate throughout their life-course, are able to, among other critical aspects, care for their bodies during menstruation such that their preferences, hygiene, comfort, privacy, and safety are supported. They should also be able to experience a positive and respectful environment in relation to the menstrual cycle, free from stigma and psychological distress and decide whether and how to participate in all spheres of life, including civil, educational, cultural, economic, social, and political, during all phases of the menstrual cycle<sup>1</sup>.

Standards for menstrual products can contribute to these by

- determining a globally relevant and acceptable definition of quality of menstrual products in terms of performance (fitness for purpose), quality and safety
- reducing barriers to availability and accessibility of products in different regions.
- contributing to a positive and constructive global narrative around menstruation and making it easier for consumers to access information about menstruation and menstrual products.

As per the report published by the World bank in Menstrual Health and Hygiene, everyday more than 300 million people menstruate worldwide, and thus, access to safe products is a prerequisite to being able to participate in and contribute to society fully, which benefits the individual and society at large. Menstrual products exist to enable people who menstruate to carry on with their normal lives, as much as possible. Menstrual products are used on or inside the body by those who have access to and can afford them. The scope of ISO/TC 338 includes all manufactured menstrual products intended for collecting or absorbing menstrual fluid during the menstrual cycle. This includes products for internal and external use as well as single- and multiple-use products. Examples of products include single and multiple use menstrual pads, tampons, panty liners, menstrual underwear, menstrual cups, menstrual discs, sponges etc.

Other products used on or inside the body like condoms, plasters and wound dressings, are highly regulated, tested and monitored<sup>2</sup>. However, there is a lack of global, harmonized standards that ensure the safety of the contents and physical properties of menstrual products for both people and the planet. Standardization in the area of

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<sup>1</sup> Hennegan J, Winkler IT, Bobel C, Keiser D, Hampton J, Larsson G, Chandra-Mouli V, Plesons M, Mahon T. Menstrual health: a definition for policy, practice, and research. *Sex Reprod Health Matters*. 2021 Dec;29(1):1911618. doi: 10.1080/26410397.2021.1911618. PMID: 33910492; PMCID: PMC8098749.

<sup>2</sup> Klintner, L. (2021). Normalizing the Natural: A study of menstrual product destigmatization. [Doctoral Thesis (monograph), Lund University School of Economics and Management, LUSEM]. MediaTryck Lund.

menstrual products is a step in the direction of broadening access to safe and effective menstrual products for all people who menstruate when and where they need them.

### 2.1.1 Diversity in markets for menstrual products

Mature markets in high-income countries (HICs) pose very different challenges than those of growth markets in low- and middle-income countries (LMICs).

Mature markets have reached saturation in terms of market penetration but offer growth opportunities on account of product innovation both in existing product categories like disposable products (pads, tampons etc.) and new categories like reusable products (menstrual cups, reusable pads and menstrual underwear etc.). Growth markets offer an opportunity for increasing 1) market penetration, 2) gender equality and 3) awareness of menstrual health. This has, in turn, spurred 1) industry investment in product innovations to reach the wide spectrum of low-, medium- and high-income consumers, 2) promotional strategies for driving aspirational demand for products, and 3) distribution strategies for reaching remote territories. However, margin pressures in growth markets, which are detailed below, also pose challenges for industry stakeholders trying to enhance product access in these markets. Standards should ensure that while people who menstruate have improved access, the performance and safety of products is not compromised on account of increasing costs of materials, distribution, innovations etc., and reducing prices to reach lower wealth quintiles.

Historically, disposable products have formed a majority share of the menstrual product market. However, new innovations are slowly catching the attention of consumers. The market share of reusable products is still fairly small across both growth and mature markets<sup>3</sup> but preliminary evidence indicates that both external and internal reusable products have good acceptability amongst consumers in growth<sup>4,5,6,7</sup> and mature markets. As innovations in existing product categories and the advent of new categories continue to grow and expand the choice available to consumers, standards should ensure that products are safe and meet common benchmarks for performance.

With growing awareness of the environmental impact of our consumption practices, consumers continuously search for more sustainable alternatives including in menstrual products. In contexts, where waste management infrastructure is still evolving, there are also environmental concerns regarding disposable menstrual products, which hold around 97 percent of the world market. The impact on wastewater infrastructure in HIC settings has also been noted. The lack of appropriate waste management systems and the variety of the different waste management systems places different demands on suitable product solutions<sup>8</sup>. A menstrual product standard can provide guidance to policy

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<sup>3</sup> <https://leap.rhsupplies.org/#/menstrual-hygiene>

<sup>4</sup> Shah, Shobha & Nair, Rajesh & Shah, Pankaj & Modi, Dhiren & Desai, Shrey & Desai, Lata. (2013). Improving quality of life with new menstrual hygiene practices among adolescent tribal girls in rural Gujarat, India. *Reproductive health matters*. 21. 205-213. 10.1016/S0968-8080(13)41691-9.

<sup>5</sup> Garikipati, S., and Boudot, C. (2017) To Pad or Not to Pad: Towards Better Sanitary Care for Women in Indian Slums. *J. Int. Dev.*, 29: 32– 51. doi: 10.1002/jid.3266.

<sup>6</sup> Hennegan, J., Dolan, C., Wu, M. et al. Schoolgirls' experience and appraisal of menstrual absorbents in rural Uganda: a cross-sectional evaluation of reusable sanitary pads. *Reprod Health* 13, 143 (2016). <https://doi.org/10.1186/s12978-016-0260-7>

<sup>7</sup> Wilson, E. & Reeve, J. & Pitt, A. & Sully, B. & Julious, S. (2012). INSPIRES: Investigating a reusable sanitary pad intervention in a rural educational setting - evaluating the acceptability and short-term effect of teaching Kenyan school girls to make reusable sanitary towels on absenteeism and other daily activities: a partial preference parallel group, cluster randomised control trial.

<sup>8</sup> [Reproductive Health Supplies Coalition. \(2022\). Webinar series on menstrual management](#)

makers and referral to already existing and accepted standards in the area (e.g., ISO 14040, ISO 17088 and any others) for appropriate handling of existing products and innovation of more sustainable menstrual products, both disposable and reusable.

The menstrual product standard(s) that ISO/TC 338 will develop can also ensure that sustainability parameters are defined so that innovation of more sustainable menstrual products – both disposable and reusable, can be encouraged. Additionally, recent research shows that menstrual product standards can enable innovation by providing entrepreneurs and product developers with a platform of safety requirements. This saves them time, effort and other resources in figuring out the measures needed to place a safe product on the market<sup>9</sup>.

Increasing consumer demand for environmentally sustainable products has also led to the emergence of products that falsely claim to be compostable and are oxo-degradable in some regions. Standards can also safeguard consumers against such products by providing reference to existing standards that define biodegradability and compostability e.g. ISO 17088.

Standards for menstrual products can also help governments achieve various Sustainable Development Goals (SDGs). Unfortunately, menstruation is not mentioned, specifically, under any of the SDGs, nonetheless, the matter can be connected to several of them and standards on menstrual products can drive the sustainable development in these areas. The most significant SDGs to menstrual products include SDGs 1 (no poverty), 3 (health and well-being), 4 (quality education), 5 (gender equality), 6 (clean water and sanitation), 10 (reduced inequalities) and 12 (responsible consumption and production)<sup>10</sup>. Ensuring that all people who menstruate have access to safe menstrual products which helps to improve menstrual health.

## 2.2 Quantitative factors

Some of the quantitative indicators that highlight the need to establish international standards for menstrual products are given below:

### 2.2.1 Demographic considerations (consumer)

Everyday 300 million people menstruate. Most people who menstruate do so between three to seven days each month for about 40 years, which amounts to around 2400 days in a lifetime, meaning a person is expected to use up to 12-15,000 single-use products in a lifetime. Aside from ensuring access to safe products and creating market pathways for different product categories, standards can enhance consumers' ability to make an informed choice, with the fundamental principle that all consumers should have this right. Additionally, standardizing menstrual products can have a destigmatizing effect, which increases gender equality<sup>11</sup>.

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<sup>9</sup> Klintner, L. (2021). Normalizing the Natural: A study of menstrual product destigmatization. [Doctoral Thesis (monograph), Lund University School of Economics and Management, LUSEM]. MediaTryck Lund.

<sup>10</sup>ISO. 2020. How ISO Standards Help Meet the SDGs. ISO: Standards. Available online: <https://www.iso.org/sdgs.html>.

<sup>11</sup>Ibid. Klintner, L. (2021).

## 2.2.2 Market size and distribution

The menstrual product market size was valued at USD 21.2 Billion in 2022 and is projected to reach USD 33.1 Billion by 2030, growing at a compound annual growth rate (CAGR) of 4.9 percent from 2023 to 2030<sup>12</sup>.

The continuing importance of mature markets in the segment of menstrual products is demonstrated by its projected market growth. According to the Annual & Sustainability Report published in 2022 by Essity AB, a leading hygiene products manufacturer, the highest usage of menstrual products was witnessed in Western Europe, followed by North America and Eastern Europe 2020<sup>13</sup>. As per the same source, women in Western Europe aged 10 to 54 use more than 380 units of menstrual products per year. Europe is projected to account for 34 percent of market growth by 2023. The United States market for menstrual products reached a size of USD 26.5 Billion in 2022 with a projected 5 year CAGR of 4.93 percent. As discussed in the section on qualitative factors, these statistics indicate that while mature markets have achieved saturation in terms of market penetration, there is significant growth potential from innovations across existing product categories like disposable pads and tampons and new consumer categories like reusable pads and menstrual cups.

The increasing importance of growth markets is reflected in both the potential for increasing market penetration and product innovations. The growing overall potential market size due to increase in menstruating population is also a contributor. In LMICs, the largest manufacturers are experiencing double-digit growth in market size annually, led by manufacturers in India and China.

Currently, there are an estimated 1.67 billion menstruators across low- and middle-income countries. 90 percent of people who menstruate in upper-middle-income countries use consumer menstrual products, compared to 62 percent in lower-middle-income countries and 39 percent in low-income countries. India and China are the two countries driving market growth in these regions overall due to the population size, manufacturing intensity and relative trade openness. Amongst lower-middle-income and upper-middle-income countries, India and China respectively account for 45-46 percent of the use of menstrual products.<sup>14</sup> Ethiopia, the Democratic Republic of the Congo, Uganda and Sudan account for 51 percent of all menstruators among all low income countries.

The total Asia Pacific market stood at USD 11.96 billion in 2020<sup>15</sup>. In 2023 by comparison, the market size of menstrual products in China alone was approximately USD 11.37

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<sup>12</sup> <https://www.verifiedmarketresearch.com/product/feminine-hygiene-products-market/>

<sup>13</sup> Essity AB. (2022). Annual and Sustainability Report [\\_essity.com/investors/reports/reportdetails/annual-reports/annual-and-sustainability-report-2022](https://essity.com/investors/reports/reportdetails/annual-reports/annual-and-sustainability-report-2022)

<sup>14</sup> Weinberger M, Eva G, Gold J, Bellows N, Reidy M, Sanders R, and Skibiak J. LEAP: Landscape and Projection of Reproductive Health Supply Needs. Reproductive Health Supplies Coalition. (2021). <https://leap.rhsupplies.org/#/menstrual-hygiene>

billion with a five-year projected CAGR of 6.16 percent<sup>15</sup> and in India, it was estimated at USD 6.2 billion with a five-year projected CAGR of 4.76 percent<sup>16</sup>.

### 2.2.3 Pressures on margins

With the changing dynamics of the global menstrual product market and efforts to improve access and affordability, there are increasing pressures on margins. It is imperative to establish standards to uphold the quality of products, ensuring they meet the necessary standards regardless of external pressures.

### 2.2.4 Distribution costs

In many lower-middle income countries, distribution and logistics infrastructure for the last mile is highly fragmented. Many manufacturers in LMICs are using highly competitive distribution strategies to reach areas where menstrual products were not commercially available till now. They include but are not limited to menstrual product dispensers and pads dispensed in the form of rolls at the point of use, last mile distribution models that include menstrual products as part of a basket of health products and services e.g. Kasha, Triggerise and many others. Other distribution strategies include leveraging traditional fast moving consumer goods (FMCG) and medical product supply chains, which also require marketers to take into account increasing distribution margins in a highly competitive category. These efforts also put additional cost pressures on manufacturers as they try to ensure that products are available at the last mile.

### 2.2.5 Import dependence

Most of the growth markets are either dependent on imports of final products or of raw materials. India, which is the largest growth market amongst LMICs, is the top importer of menstrual pad raw materials in terms of number of import shipments, followed by Bangladesh and Vietnam<sup>17</sup>. China and the United States of America are the key exporters of materials. Many LMICs, including those that have manufacturing capacity like India and Vietnam, are also dependent on import of the finished products. Uganda, Sri Lanka, India, Namibia, Pakistan, Bangladesh, Kenya are some of the largest importers of menstrual pads globally (in terms of number of shipments) and India, China and South Africa are the largest exporters<sup>18</sup>. This means that in many of these countries, higher export and import taxes put additional pressures on margins, especially in LMICs where consumers are more price sensitive. After the COVID19 crisis, global supply chains have also been challenged and the cost of logistics has exacerbated these pressures.

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<sup>15</sup> <https://www.statista.com/outlook/cmo/tissue-hygiene-paper/feminine-hygiene/china>

<sup>16</sup> <https://www.statista.com/outlook/cmo/tissue-hygiene-paper/feminine-hygiene/india>

<sup>17</sup> <https://www.volza.com/p/sanitary-napkin-raw-material/import/>

For example, as of the date of the publication of this document, India has at least 20 disposable menstrual pad brands, 16 reusable menstrual pad brands, 5 tampon brands and 24 menstrual cup brands. Similarly, Kenya, Nigeria and Tanzania have 25, 19 and 13 disposable menstrual pad brands respectively also. (Report to RHSC Landscaping Supply Side Factors To Menstrual Health Access, June 2021, Mann Global Health, Page No: 11)

<sup>18</sup> <https://www.volza.com/p/sanitary-pads/buyers/>

### 2.2.6 High degree of competition

In addition to the cost and pricing constraints that influence individual market players, the sheer number of players that have entered the market across different product types has increased competition in the industry manifold. In most LMICs, the majority market share belongs to the large multinational corporations. However, slowly there are a number of local brands - either locally manufactured or imported that have grown and captured some market share. In India and a few other countries, there has also been an impetus for small scale cottage industries to manufacture and distribute disposable and reusable sanitary pads.

The increasing numbers of small and medium sized players have led to improved access to affordable products. However, without clarity on safety requirements for menstrual products, it has also led to unregulated products with unsubstantiated claims coming into the market, especially in the case of LMICs. Standardization can help ensure that while access to affordable products is improved, quality is assured simultaneously.

In higher income countries, sustainability related innovation is one of the key drivers of growth in disposable and reusable menstrual product categories.<sup>19</sup> In this context, research and development costs in a highly competitive market can put additional pressures on margins. Standards can ensure that quality and innovation go hand in hand as part of such development efforts.

### 2.2.7 Existing regulations<sup>20, 21</sup>

Many countries have standards for disposable menstrual pads but only a few countries in Africa and India have developed standards for reusable menstrual pads. Some regulation is available on insertion products from the US FDA and Standards Australia - namely tampons and menstrual cups respectively. The United Nations General Marketplace now offers technical specifications for disposable and reusable sanitary pads, tampons and menstrual cups. Within the EU there is a voluntary label manufacturer can apply for, called the EU Ecolabel. In Europe there is also an association of the nonwovens and related industries (EDANA) which has developed a code of practice for tampon manufacturers and a guide for supply chain information for absorbent hygiene care products.

In Japan menstrual products are included in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. In Japan menstrual pads are classified as quasi drugs while tampons and menstrual cups are classified as medical devices. However, across the board, there is a high degree of variability in the specifications covered in standards in different countries.

Regulatory and economic classification of products also varies widely. Menstrual products are mostly categorized as medical devices, therapeutic goods or consumer products in different countries and regions. For example, in most European countries they fall under the General Product Safety Regulation, which means there is no obligation for manufacturers to list the composition of the product or perform biocompatibility testing.

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<sup>19</sup> Ibid. Essity AB Annual and Sustainability Report. (2022).

<sup>20</sup> Mahajan T, Joshi S. 2021. Development and compliance of standards for menstrual products in South Asia and Africa. Development Solutions Inc. and Reproductive Health Supplies Coalition

<sup>21</sup> Original proposal for TC 338

When this standard is published, the regulation will be in place. Whereas in the USA menstrual products are considered a medical device, with additional testing requirements. There are also countries that classify menstrual products in other categories, for example the legislation in Thailand covering this area is the Ministry of Public Health's Cosmetic Act. In Australia there is specific legislation for tampons, where all tampons on the internal market need to comply with Therapeutic Goods (Standards for Tampons) (TGO 103). In Japan menstrual products are included in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. A list of known national and/or regional regulations and standards on menstrual products (not comprehensive) is given in Annexure A.

Given the complexity and variability in classification and specifications around the world, and in many instances lack of clear requirements, ISO standardization can help bridge the gap where regulations are not clear or strong enough.

An international standard in the area of menstrual products would be useful in addressing the issues identified above, as requirements of testing and transparency can reduce the information asymmetry between producers and consumers regarding product safety, performance and fitness to purpose. These matters should be addressed on a global level, since they apply to all consumers of these products, globally.<sup>22</sup>

### **3 Benefits expected from the work of the ISO/TC**

The principal benefit expected from the work of ISO/TC 338 is the standardization in the field of menstrual products and the future deliverables produced by the committee contribute to the improvement of safety, quality and performance of menstrual products. The standard is expected to benefit all stakeholder categories including consumers, manufacturers, other supply chain stakeholders, governments, and the environment. Anticipated benefits of the work of ISO/TC 338 committee include but are not limited to:

- Addressing the widespread gap in standardization of menstrual products for safety, fitness for purpose and quality control globally, which will drive demand.
- Creation of a common definition of fitness of purpose and safety of menstrual products for use by the consumer.
- Increasing consumers' ability to make informed choices, with the fundamental principle that all consumers should have this right, and the associated consumer protections.
- Destigmatizing menstruation and menstrual products, contributing to greater gender equality.
- Filling gaps and/or harmonizing national and regional standards, reducing the duplication of standards work at national level and gaining learning opportunities across borders.
- Facilitating trade and increasing market access by reducing regulatory barriers and cost involved in conducting business across geographies.

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<sup>22</sup> Ibid. Klintner, L. (2021).

- Ensuring that the minimum requirements are the same all over the world and facilitate fair practices in international trade of commodities.
- Stimulating innovation by providing market newcomers with a platform of safety requirements, cutting back on their time to market.
- Diversifying the product offering on a historically homogeneous market as a result of increased innovation.
- Supports producers and manufacturers to move towards the design and production of less environmentally impactful menstrual products.
- Supporting Governments in reaching Sustainable Development Goals including but not limited to those related to Gender, WASH, Health and Education.

## **4 Representation and participation in the ISO/TC**

### **4.1 Membership**

ISO/TC 338 committee at present has 27 Participating members and 18 Observing members (as of 2024-03-08). The list of current members of the TC and their corresponding national standards bodies may be accessed at:

<https://www.iso.org/committee/8933440.html?view=participation>

### **4.2 Analysis of the participation**

ISO/TC 338 TC committee works towards increasing stakeholder engagement to reflect the complexity, size, requirements, needs and diversity.

ISO/TC 338 identifies, recognizes and appreciates the importance of broad representation of members from different regions of the world. The current composition of the committee contains representation from North America, South America, the Middle East, Australia, Africa, Europe and Asia. The committee continuously works towards a well-balanced geographical spread by seeking participation from LMICs, small- and medium-sized enterprises (SMEs), stakeholders including manufacturers of different types of menstrual products, technical experts for different aspects of performance, safety (materials, bio-burden, environmental etc) and health, consumers and government to a greater degree.

### **4.3. Liaison relationship**

Existing liaison relationships are:

- UNFPA - United Nations Population Fund
- EDANA 'European Disposables and Nonwovens Association – EDANA'

These ISO committees have been identified as collaboration partners, however not overlapping in scope.

Liaison Committees to ISO/TC 338:

- ISO/TC 6 Paper, board and pulps

- ISO/TC 6/SC 2 Test methods and quality specifications for paper and board
- ISO/TC 173/SC 3 Aids for ostomy and incontinence

Liaison Committees from ISO/TC 338:

- ISO/TC 38 Textiles
- ISO/TC 133 Clothing sizing systems - size designation, size measurement methods and digital fittings
- ISO/TC 157 Non-systemic contraceptives and STI barrier prophylactics
- ISO/TC 173/SC 3 Aids for ostomy and incontinence
- ISO/TC 194 Biological and clinical evaluation of medical devices
- ISO/TC 210 Quality management and corresponding general aspects for products with a health purpose including medical devices

## **5 Objectives of the ISO/TC and strategies for their achievement**

### **5.1 Defined objectives of the ISO/TC**

1. To create standards for menstrual products that meet the requirements of the industry, as well as consumers and other concerned stakeholders throughout the world.
2. To identify terminology and prepare definitions for standardization in the field of menstrual products.
3. To provide clear guidance to menstrual product manufacturers on the safety, performance of menstrual products and reference to existing guidelines on manufacturing processes.
4. To provide clear guidance to the testing laboratories on the methods of evaluation of performance of different menstrual products and consumers on the safety requirement of menstrual products.
5. To continue working closely with other ISO/TCs to avoid repetition and conflict.

### **5.2 Identified strategies to achieve the ISO/TC's defined objectives**

ISO/TC 338 intends to use a variety of strategies to achieve its objectives and create overall priorities for the TC. The strategies will include but will not be limited to the following:

- a. Prioritizing the project by forming different groups such as task group, working group etc to discuss and deliberate various sections of the standards such as scope, terms and definition and technical details. Size of each group may be decided by the TC. In the case of working group, when deciding on the size, TC may consider setting the maximum number of experts per each P-member and liaison organization (and committee). For other groups, TC is suggested to

- approve the composition of the group as the same time as the establishment to have the composition clear from the beginning of the specific group.
- b. Wherever possible, parallel meetings would be planned with the task group and working group with the experts from different fraternities. Further, comments would be accepted pre and post meeting (before the working document is submitted for voting) to help members from geographic locations in different time zones. This would assist ISO to come up with the standard within scheduled time.
  - c. Working groups with a small group of experts would also be planned to draft the working document which would be further discussed in the main meeting. This would ease the process of discussion and finalization in the main meeting.
  - d. Wherever required and available, data published in reputed research journals, magazines and output of in-house R&D from members and external experts etc. will be considered while drafting technical specifications.
  - e. Regulatory requirements of different countries would also be taken into account while drafting the working document.
  - f. Develop consensus on terminologies used among different stakeholders engaged in the standardization to ensure equitable representation of consumer interests.
  - g. Arrangement for physical plenary meetings would be planned at least once in an year with the option to attend virtually to allow for maximum participation.
  - h. For work-items and projects, virtual meetings or hybrid meetings will be encouraged and the frequency of the meeting for task groups and work groups would be increased to ensure development of outputs in a timely manner.
  - i. Project teams will be developed for each work-item with a designated project leader for efficient and timely completion of outputs.
  - j. Attempting to liaise with as many other relevant TCs as necessary to carry out the work of the technical committee and liaising with other global organizations outside of TCs as is appropriate and practical.
  - k. Increasing LMIC participation by:
    - ✓ Exploring the feasibility of scheduling plenary meetings in conjunction with other ISO TCs and members whenever feasible and ensuring that the meetings are also organized in Low- and Middle-Income Countries (LMICs).
    - ✓ Capacity building initiatives from ISO and SIS as well as advocacy in the menstrual health community to encourage LMICs to participate in ISO/TC 338.

## **6 Factors affecting completion and implementation of the ISO/TC work programme**

The following factors have been identified which may affect, to a lesser or greater degree, the development of standards in accordance with the objectives and strategies of this business plan:

- a) Many types of products are covered in the scope of ISO/TC 338. This implies challenges of applicability of test methods, raw materials, relevant expertise, etc. to the various product categories. Additionally, scientific data is not publicly available equally for all product categories. Specifications within product categories will also vary.
- b) Variance in legal classification and related regulatory frameworks of menstrual products from consumer products to medical devices across countries can affect the approach towards creation and final implementation of the standard.
- c) Variation in legislation and infrastructure relating to disposal and waste management of menstrual products across country and regional contexts may affect the implementation of the standard.
- d) Increased cost of testing to comply with the standard may limit adoption among SMEs.
- e) Stigmatization of menstruation affects the standardization, adoption and implementation at every level.
- f) Technical specifications established in different countries and regions can reflect social and cultural norms and pose barriers for harmonization under one unifying standard.

## **7 Structure, current projects and publications of the ISO/TC**

### **7.1 Overall Structure of the TC**

The current structure of ISO/TC 338 is:

- AHG 1 Terminology
- TG 1 Strategic Business Plan
- WG 1 General Requirements

The ISO Central secretariat oversees global standards development. The Technical Management Board (TMB) reports to the Central Secretariat and oversees TC operations. ISO/TC 338 develops ISO standards and is administered by Swedish Institute for Standards (SIS). The ISO/TC 338 oversees work groups that develop menstrual product standards. The working groups and task groups take on topics that are discussed and voted on by participating countries and national standard boards and mirror committees.

## 7.2 Current projects and publications

Ad Hoc, Task- and working groups of ISO/TC 338:

### Ad Hoc Group 1 Terminology

- an ad hoc group works on the related terminologies and defining terms related to menstrual products.

### Task Group 1 Strategic Business Plan

- a task group to draft the ISO/TC 338 Strategic business plan.

### Working Group 1 Safety, performance and general requirements of menstrual products

- a working group developing standard for general and safety requirements for menstrual products from a user perspective, the scope covers both internally and externally used products intended for single and multiple use.

## 7.3 Stakeholders

Priority stakeholders for the current work programme are identified as:

- National, regional and international consumer representation bodies
- Academic and Research bodies
- Representations from industry and commerce, including manufacturers and other supply chain stakeholders
- Government representatives

### Information on ISO online

The link below is to the TC's page on ISO's website:

<https://www.iso.org/committee/8933440.html>

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- About (Secretariat, Committee Manager, Chair, Date of creation, Scope, etc.)
- Contact details
- Structure (Subcommittees and working groups)
- Liaisons
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- Work programme (published standards and standards under development)

### Reference information

[Glossary of terms and abbreviations used in ISO/TC Business Plans](#)

[General information on the principles of ISO's technical work](#)

**Annexure A**

	<b>Country</b>	<b>Standard</b>	<b>Authority</b>
1.	Australia	AS 2869:2008 Tampons - Menstrual Therapeutic Goods (Standard for Menstrual Cups) Order 2018 (Therapeutic Goods Order 99)	Standards Australia (SA)
2.	ARSO**	DARS 653:2017 for disposable sanitary napkins DARS 1575:2017 for reusable sanitary napkins	African Organization for Standardization (ARSO)
3.	Bangladesh	BDS 1261:2016 Sanitary Towels Mandatory	Bangladesh Standards and Testing Institution (BSTI)
4.	China	GB/T 8939—2018 , Sanitary absorbent pads (panty liner) GB/T 39391—2020, Sanitary absorbent pants GB/T 43585–2023 Disposable tampons	Standardization Administration of China (SAC)
5.	East African Community*	EAS 96-1:2018, Sanitary towels — Specification — Part 1: Disposable	East African Standards Committee (EAC)
6.	European Union	EU Ecolabel for Absorbent hygiene products and reusable menstrual cups	EU Ecolabel
7.	Egypt	ES:2023 TAMPONS	Egyptian Organization for Standardization and Quality (EOS)
8.	Ethiopia	ES: 6345- Sanitary Pads-Specification- Disposable (2018) ES: 6346- Sanitary Pads-Specification- Reusable (2018)	Ethiopian standards Institute (IES)
9.	Finland	Nordic Swan Ecolabel Sanitary Products 023	Nordic Eco Labelling
10.	Ghana	GS 1248:2019: Specification for single-use disposable sanitary towels (pads) for external use	Ghana Standards Authority (GSA)

11.	Indonesia	SNI 16-6363-2000: Sanitary Pads (2000, was taken under revision in 2015)	National Standardization Agency of Indonesia (Badan National Standardisasi – BSN)
12.	India	IS 5405:2019 for disposable sanitary napkins (1980, revised in 2019)	Bureau of Indian Standards (BIS)
		IS 17514:2021 for reusable sanitary napkins	
13.	Japan	PFSB No. 0325-17: Standards for Approval of Sanitary Napkins (2015)	Ministry of Health, Labour and Welfare
14.	Kenya	DKS: 2881- Disposable Maternity Pads- Specification (2018)	Kenya Bureau of Standards (KEBS)
		KS 2925:2020- Kenya Standard-Textiles-Reusable Sanitary Towels-Specification First Edition (2020)	
15.	Malawi	MS 890:2013 SANITARY TOWELS – SPECIFICATION (2013)	Malawi Bureau of Standards (MBS)
		MS 1445:2018- Reusable sanitary towels-Specification (2018)	
16.	Nigeria	NIS 291 (2018) Disposable Sanitary Pads	Standards Organisation of Nigeria (SON)
17.	Pakistan	PS:1449-1979 for disposable sanitary napkins	Pakistan Standards and Quality Control Authority (PSQCA)
18.	South Africa	SANS: 1043 for disposable sanitary napkins (2010)	South Africa Bureau of Standards (SABS)
		SANS: 1812 for reusable sanitary napkins (2019)	
19.	South Korea	MFDS Quasi-drugs Group 1 (A) (2009)	Korean Ministry of Food and Drug Safety
20.	Sri Lanka	SLS 1732: 2022 - Single-use sanitary towels	Sri Lanka Standards Institution (SLSI)
		SLS 1748: 2023 - Single-use Panty liners	
		SLS 1749: 2023 - Single –use Ultra-thin/slim sanitary towels	
21.	Tanzania	TZS: 1659- Disposable Sanitary Towels - Specifications (2014)	Tanzania Bureau of Standards (TBS)
		TBS: 6136- Reusable Sanitary Towels – Specifications (2nd Edition - 2019)	
22.	United States of America	Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) (2005)	US FDA

23.	UNGM	Technical Specifications for Disposable Sanitary pads, Reusable Menstrual Pads and Menstrual cups (2021)	UNICEF, UNFPA, UNHCR
24.	Uganda	US EAS 96-1:2018, Sanitary towels — Specification — Part 1: Disposable	Uganda National Bureau of Standards (UNBS)
		US 1782:2017, Reusable sanitary towels — Specification US 2863:2023, Tampon — Specification	
		US 2381: 2023, Reusable menstrual cup — Specification	
25.	Vietnam	TCVN 10585:2014 Sanitary Pads for Women	Directorate for Standards, Metrology and Quality (TCVN)
26.	Zambia	HS Code: 4818.40 (import guidelines 2011) for sanitary napkins	Zambia Bureau of Standards (ZABS)
27.	Zimbabwe	ZWS: 730- Manufacture of Sanitary Pads (2015)	Standards Association of Zimbabwe (SAZ)
		ZWS 1023: Reusable sanitary pads (2019)	

\*Burundi, Kenya, Rwanda, South Sudan, Tanzania, Uganda

\*\*36 member countries of United Nations Economic Commission for Africa and the African Union