

DRAFT UGANDA STANDARD

First Edition
2022-mm-dd

Reusable menstrual cup — Specification



Reference number
DUS 2381: 2022

© UNBS 2022

Compliance with this standard does not, of itself confer immunity from legal obligations

A Uganda Standard does not purport to include all necessary provisions of a contract. Users are responsible for its correct application

© UNBS 2022

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilised in any form or by any means, electronic or mechanical, including photocopying and microfilm, without prior written permission from UNBS.

Requests for permission to reproduce this document should be addressed to

The Executive Director
Uganda National Bureau of Standards
P.O. Box 6329
Kampala
Uganda
Tel: +256 417 333 250/1/2
Fax: +256 414 286 123
E-mail: info@unbs.go.ug
Web: www.unbs.go.ug

Foreword

Uganda National Bureau of Standards (UNBS) is a parastatal under the Ministry of Trade, Industry and Cooperatives established under Cap 327, of the Laws of Uganda, as amended. UNBS is mandated to coordinate the elaboration of standards and is

- (a) a member of International Organisation for Standardisation (ISO);
- (b) a contact point for the WHO/FAO Codex Alimentarius Commission on Food Standards; and
- (c) the National Enquiry Point on TBT Agreement of the World Trade Organisation (WTO).

The work of preparing Uganda Standards is carried out through Technical Committees. A Technical Committee is established to deliberate on standards in a given field or area and consists of key stakeholders including government, academia, consumer groups, private sector and other interested parties.

Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC 315, *Textiles and related products*.

Introduction

Many girls and women do not have access to appropriate menstrual health management (MHM) products, i.e., products that are effective, comfortable, affordable and safe to use, leaving them to resort to products available, often of a poor quality. The lack of appropriate MHM products can have far-reaching implications for women and girls in the physical, social and mental wellbeing, as well as for their sexual reproductive health and rights. Women and girls' capacity to manage their periods is affected by many factors, including taboos about the subject, limited access to affordable and hygienic MHM products and lack of proper disposal options of products. This can have far-reaching implications for women and girls' physical, social and mental wellbeing, as well as for their sexual reproductive health and rights.

These MHM issues are often further exacerbated by insufficient access to safe and private toilets, and lack of clean water and soap for personal hygiene. As a result, many women and girls have to manage their periods in ineffective, uncomfortable and unhygienic ways, contributing to them feeling shame and restricting them from reaching their full potential in social, school and work settings.

The menstrual cup is not a new innovation. But in recent years, it has increasingly been introduced as a more sustainable way to improve the MHM of women and girls in low-income contexts. It is a bell-shaped cup, usually made of medical-grade silicone which is inserted in the vagina during menstruation to collect menstrual flow. A menstrual cup can be worn for up to 12 hours before emptying depending on one's flow. Once the user becomes familiar with its use, it is comfortable and unobtrusive and can be easily washed and stored, for up to ten years.

There are both disposable and reusable menstrual cups.

Reusable menstrual cup — Specification

1 Scope

This Draft Uganda Standard specifies requirements, sampling and test methods for reusable menstrual cups.

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 14362-1, *Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres*

ISO 14362-3, *Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 3: Detection of the use of certain azo colorants, which may release 4-aminoazobenzene*

ISO 16373-1, *Textiles — Dyestuffs — Part 1: General principles of testing coloured textiles for dyestuff identification*

ISO 16373-2, *Textiles — Dyestuffs — Part 2: General method for the determination of extractable dyestuffs including allergenic and carcinogenic dyestuffs (method using pyridine-water)*

ISO 16373-3, *Textiles — Dyestuffs — Part 3: Method for determination of certain carcinogenic dyestuffs (method using triethylamine/methanol)*

US ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

US ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

US ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

US ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for skin sensitization*

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 <http://www.iso.org/obp>

menstrual cup

bell-shaped cup, usually made of medical-grade silicone which is inserted in the vagina during menstruation to collect menstrual flow

4 Requirements

4.1 General requirements

4.1.1 Reusable menstrual cups shall be made out of surgical rubber, thermoplastic elastomer (TPE) or medical grade silicone.

4.1.2 The materials used for making reusable menstrual cups shall be inert to avoid reactions with materials they come in contact with.

4.2 Specific requirements

4.2.1 Dimensions

4.2.1.1 A typical shape of a menstrual cup is shown in Figure.1.

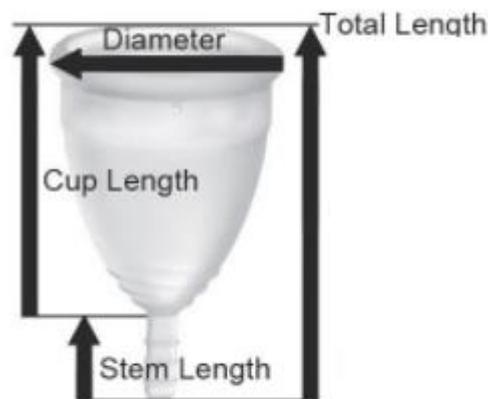


Figure 1 — An illustration of a typical menstrual cup

4.2.1.2 When measured with the aid of a micrometre screw gauge, the menstrual cup shall comply with the dimensions declared on the label subject to a tolerance of $\pm 2\%$

4.2.1.3 The wall thickness shall be between 1.5 mm – 2.5 mm when measured with the aid of a micrometre screw gauge.

4.2.2 Capacity

When filled with clean water, a menstrual cup shall comply with the volume of flow declared on the label.

4.2.3 Biocompatibility

When tested in accordance with US ISO10993-1, ISO 10993-5 and ISO 10993-10, the reusable menstrual cup shall be not be cytotoxic nor cause sensitization or mucosal irritation.

4.2.4 Sterilization

Reusable menstrual cups shall be able to withstand the high temperatures of sterilization subject to 121 °C for 20 mins or 134 °C for 3 mins.

4.2.5 Restricted colourants

Dyed reusable menstrual cups shall be free from listed restricted colourants, when tested in accordance with ISO 14632-1, ISO 14632-3, ISO 16373-2 and ISO 16373-3.

Colourants on reusable menstrual cups shall be identified and classified in accordance with ISO 16373-1

5 Packaging

Reusable menstrual cups shall be individually wrapped in suitable packaging to ensure that the hygienic quality and physical integrity of the product is maintained.

6 Labelling

Each menstrual cup pack shall be legibly and indelibly labelled with the following information:

- a) name and address of the manufacturer;
- b) product name, i.e. reusable menstrual cup;
- c) volume of flow that can be collected;
- d) dimensions (i.e. cup length, stem length (where applicable), diameter and wall thickness);
- e) material composition (i.e. rubber or medical grade silicone);
- f) Warning concerning the hazards of menstrually related Toxic Shock Syndrome (TSS) such as, "Menstrual cup use is associated with the Toxic Shock Syndrome. The potentially fatal disease causes women to experience fever, shock, low blood pressure, skin rashes, liver and kidney abnormalities";
- g) country of origin/manufacture;
- h) care and use instructions, including the emphasis on the importance of personal hygiene, particularly the washing of hands before and after inserting the menstrual cup. (Pictorials are recommended);
- i) storage instructions;
- j) guidance and recommendations on selection of a suitable size for one's flow and the range of other available sizes (see Annex A for more understanding of the factors affecting selection of sizes);
- k) instructions for IUD users
- l) date of manufacture
- m) Lot/batch number

7 Sampling and criteria for conformity

Sampling shall be done in accordance with US ISO 2859-1

Annex A (informative)

Reusable menstrual cup sizing guidelines and recommendations

Regarding personal choice and needs in size or sizes of menstrual cups, there are no absolute rules or guidelines that will guarantee a perfect fit.

The vagina does not change size from adolescence to adulthood. What we are born with, that is the length of the vagina does not change after maturity. Muscles may be firmer or looser depending on many factors such as fitness level, time just after a vaginal birth. The best size determination is done by trial testing.

Most menstrual cup brands come in two or three size ranges. These are 15ml and 25ml menstrual cups based on volume. Some companies offer a 30ml volume for those with a very heavy flow. Table A.1 describes the factors to be considered when determining a menstrual cup size.

Table 1 — Factors to be considered when determining a menstrual cup size

Factor	Recommendation
Age	Small and medium sizes are recommended for young girls while large sizes are recommended for adults. However, other factors should be factored in such as fitness activity level since pelvic floor muscles may weaken over time.
Volume of menstrual flow	A lighter flow — where the need to change a regular pad a couple of times a day — usually equates to a smaller menstrual cup. A heavy flow — where the need to change a high absorbency pad every 2 to 3 hours — is often more suited to larger cup sizes.
Vaginal birth	Many adolescents who have not experienced a vaginal birth use a 25ml cup while many who have use a 15ml cup. Pelvic floor muscles may weaken after a vaginal delivery, but this is not an absolute determinant.
Cervix height/ length of vaginal canal ^a	A higher sitting cervix may indicate the need for the cup with a longer dimension for ease of removal, whereas conversely, a shorter vaginal canal i.e., Lower positioned cervix may require a menstrual cup with a shorter profile.
Fitness status	This can influence the tightness of the pelvic floor muscles. Active individuals may find they are fine with a smaller volume menstrual cup but this should be factored in with individual level of menstrual flow. Whereas a menstrual cup that is too small may result in leaking, conversely, a larger cup may lead to mild cramping or feelings of slight discomfort.
Cup length and diameter	Length and diameter of menstrual cups vary from manufacturer to manufacture. If a cup's length is too long, it may touch the cervix and the stem may be felt externally by vulva. Both occurrences will lead to discomfort as the menstrual cup should be positioned below the cervix, not in

	<p>contact with it.</p> <p>A user should not feel a menstrual cup when it is properly positioned in the vagina. To note, if a menstrual cup is slightly too long and the stem is protruding outside the body, the stem of most cups can be removed without affecting the overall functionality of the device.</p> <p>Regarding diameter, the width at the opening of the menstrual cup should be wide enough to securely fit and stay in place in the vagina. If the diameter is too narrow, leaking may be experienced. If it is too wide, it may lead to discomfort and overstimulate the nearby urethra causing a sensation of needing to urinate.</p>
Softness/ firmness	<p>Silicone menstrual cups come in a range of softness to firmness. If too soft, the cup may fail to open at insertion thus potentially lead to leaking and discomfort.</p> <p>Likewise, a cup that is too firm may be a best choice for the more athletic user but may add to the challenge of folding for easy insertion.</p> <p>Menstrual Cups made with TPE have a standard flexibility that again is in the medium range of firmness.</p>
<p>^a To determine length of vaginal canal, that is, whether the cervix is sitting high or low, insert your longest finger into your vagina on or just before the first day of your period and feel for your cervix. It will be at the top of your vaginal canal and should feel similar to the tip of your nose —a smooth raised part with a dimple in the middle. If your finger has to go all the way in before you reach your cervix, you likely have a high cervix. But if you reach it at the first knuckle, it's likely low. In between is average.</p>	

Certification marking

Products that conform to Uganda standards may be marked with Uganda National Bureau of Standards (UNBS) Certification Mark shown in the figure below.

The use of the UNBS Certification Mark is governed by the Standards Act, and the Regulations made thereunder. This mark can be used only by those licensed under the certification mark scheme operated by the Uganda National Bureau of Standards and in conjunction with the relevant Uganda Standard. The presence of this mark on a product or in relation to a product is an assurance that the goods comply with the requirements of that standard under a system of supervision, control and testing in accordance with the certification mark scheme of the Uganda National Bureau of Standards. UNBS marked products are continually checked by UNBS for conformity to that standard.

Further particulars of the terms and conditions of licensing may be obtained from the Director, Uganda National Bureau of Standards.



Public Review Draft

ICS 11.020

Price based on nn pages