

## Technical Specifications for Disposable Sanitary pads

### General description

Female disposable (single use) sanitary pads with wings to manage menstruation and to maintain a menstrual health. Supplied as unscented menstrual pads.

### Product Specification

The product shall consist of a top layer which comes in direct contact with the body, a transfer layer followed by an absorbent material which absorbs menstrual blood and other fluids, a leak proof layer at the bottom and an adhesive coating at the back of leak proof layer for fixing to the panties, which prevents dislocation when worn. The pad shall have wings so that it could be attached to the panties.

The upper layer (top layer) is a woven or non-woven material with sufficient porosity to meet the absorbency requirements. The materials for the top layer may include polyester, polyethylene or polypropylene or their blend, cotton, viscose/rayon etc. Middle absorbent layer made of cellulosic material and outer layers made of plastic. Optionally, the absorbent layer can be mixed with super absorbent polymers to enhance absorption and make the pad thin. The lower leak proof layer including the wings is made of plastic such as polyethylene/polypropylene. The leak proof layer and the wings are coated with a synthetic resin adhesive/glue, which is laminated with a silicone coated release paper liner or similar adhesive release liners. The adhesive shall provide sufficient tack to retain the mounted pad to the fabric surface of the crotch of the undergarment. Each pad may be folded and shall be provided with a pull away cover, preferably environment friendly, for disposal of pads after use.

The product shall be white in color for most of the areas and shall be free from unpleasant odor. It shall not contain any foreign matter such as dust and particulate matter. It shall be safe for skin contact and shall not cause any allergy or irritation and applicable standards shall be referred while selection of raw materials. Difference in color, size or odor shall not allowed among the products. The sanitary napkins shall be free from acids and alkali, shall have sufficient absorbency to manage normal to heavy flow, the adhesive layer is sufficiently strong so that no dislocation happens while use and the product shall not disintegrate within the recommended wear time. The adhesive layer shall not leave adhesive residues on the panties while removal of pads.

Product shall be unscented only. Wear Time: Shall be able to wear for 4-6 hours.

The total viable bacterial count, when determined in accordance with EN ISO 6887-1 or equivalent shall not exceed 1000 CFU per gram of sanitary pad/towel; and shall be free from Enterobacteriaceae, Staphylococcus aureus, candida albicans and Pseudomonas aeruginosa etc.

Absorbency shall be tested using colored water or oxalated sheep or goat blood or test fluid when poured on to the center of the napkin (at the rate of 15 ml per minute) and it shall not show up at the bottom or sides of the sanitary napkin (test method is indicative only). Submit the absorbency values, weight of the pad and test method used during the submission.

### References

ES 6345:2018 - Ethiopian standard

<https://www.rhsupplies.org/news-events/news/standards-for-menstrual-health-products-1698/>

Sanitary Towels- East African Standard EAS 96:2008

FDA GUIDANCE DOCUMENT - Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff JULY

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The absorbency values shall be comparable to the same sample sizes that are available in the market or tested at an accredited lab as per ISO 17025. The pad shall have enough fluid retention capacity under pressure, details under size and absorbency capacity.

Shelf life shall be minimum 3 years from date of production with minimum 80% of total shelf life on delivery.

pH of the extract should be 6-8.5 when tested according to EN ISO 3071, Method B.

A claim on biodegradability and composting for the product shall be accompanied with independent third-party certification as per applicable ISO/EN standards.

### Size and absorbent capacity

**Regular:** Size and absorbent capacity must be suitable for normal flow. Regular size should have length 180mm to 220mm and width excluding wings shall be 60mm–100mm.

Absorbency shall be 15-20ml when measured as per standard test method mentioned above.

**Large:** Size and absorbent capacity must be suitable for moderate flow. Large size with length 220mm to 260mm and width excluding wings shall be 60mm–100mm.

Absorbency shall be 20-30 ml when measured as per standard test method mentioned above.

**Extra Large:** Size and absorbent capacity must be suitable for heavy flow. Extra-large size with length 260mm to 300mm and width excluding wings shall be 60mm–100mm.

Absorbency shall be 30-40 ml when measured as per standard test method mentioned above.

### Instructions for use

Must be multilingual: English, French, Arabic and Spanish.

Shall have details such as the method of use and wear time, Indication as to which side is absorbent and disposal instructions. Caution statement to indicate that the pad after use shall not be washed and reused and not to be shared. Safety and warning statements on the primary packaging. Instruction for use and care as a QR code or pictograms (preferable to have).

### Accessories/ Spare Parts/Consumables

N/A

### Packaging and labelling

**Primary packaging:** 10 one size units per pack. Primary package shall be a plastic type with good seal integrity to protect the item from moisture and contamination during storage and transportation. The instructions of use to be supplied as an insert in the primary packaging.

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Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff JULY

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**Labelling:** Printing on primary packing shall have manufacturers name and address, product name, size of the pad, Lot/batch No, Date, month and year of manufacture, expiration date, Number of Napkins, user instructions, caution statements.

**Secondary packaging:** Marking as specified in contract. Printing on secondary Packaging shall include Generic name of product, Lot/Batch No, Date, month and year of manufacture, Expiration date, month and year, Manufacturer's name and address, Consignee address, Number of primary packages, Gross weight.

### Regulation and Conformity Requirements

Applicable QMS standards ISO 9001 minimum.

### Classification

FDA regulates sanitary pads as Class I medical device. In the European Union sanitary pads are regulated as consumer products (General Product Safety Directive 2001/95/EC).

### Safety and Product Standards, must comply with the following standards

Product comes in close contact with skin and mucosa hence, shall not harm vaginal flora or lead to reproductive tract infections (RTIs) through growth of harmful microbes.

For any pad materials that are bleached during processing, the supplier should identify the bleaching process used, e.g., Elemental Chlorine-Free (ECF) or Totally Chlorine-Free (TCF) and shall provide safety data. Shall be free from formaldehyde, heavy metals, polycyclic aromatic hydrocarbons (PAHs) phthalates, dioxins, acrylic monomers, reproductive & developmental toxins and other carcinogens. Shall be compliant as per as per REACH regulations (preferable to have a REACH compliant certificate issued by the competent authority).

ISO 10993 Part-5&10: Evaluation and Testing to assess the safety.

ISO 6887-1:2017 Microbiology of the food chain — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination or equivalent

ISO 6888-1:1999/AMD 2:2018 Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus* and other species) or equivalent.

ISO 17088:2008- Specifications for compostable plastics or equivalent.

### Environmental Requirements

EU Ecolabel, Sustainable, recycled, re-used or reusable materials for packaging and the manufacturer of the disposable pad preferably shall be in compliance with ISO 14001.

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