ASSISTIVE PRODUCT SPECIFICATION FOR PROCUREMENT

Single-use Absorbent Product

Objective:

The objective of this specification is to help organizations in procuring good quality single-use absorbent products that assist the individuals with moderate or heavy incontinence.

World Health Organization

1. Product description

The purpose of this section is to provide specific key details relevant to the assistive product so that it is easily identifiable.	
Purpose of 1.1	Name of product as per WHO priority APL and/or commonly used names.
1.1 Name of product	Single-use absorbent incontinence products
Purpose of 1.2	As per ISO 9999 classification and terminology document (refer https://www.iso.org/standard/60547.html).
1.2 ISO 9999 code	Assistive products for absorbing urine and/or containing faeces (as described in ISO9999) [09 30]: - Pads⁺ (insert type, single-use) that are held in place by elastic mesh briefs or close-fitting underwear. [09 30 18] - Pads (all-in-one, single use, elastic waist and legs) secured with fastener system (self-adhesive or hook and loop tabs) also known as wraparound⁺, diaper (adult version of product for infants), adult briefs, slips). [09 30 21] - Fixation underwear for securing insert type pads. 09 30 39] ⁺ Proposed terms for International Continence Society Standardisation of terminology for single-use absorbent products. Note: ISO 9999 is under revision. If the revision adopts any new category names, the new categories should be used (if relevant).
Purpose of 1.3	Describes the product type in clear, simple, easily understood language and the intended use in addressing functional needs.
1.3 Description and intended use	Absorbent incontinence products designed to absorb and/or contain moderate or heavy urine loss and/or any faeces. Their purpose is to protect the user's clothes and environment thereby preserving the dignity, comfort and quality of life of the user and (if applicable) their caregiver(s) and promoting social inclusion.
Purpose of 1.4	Refers to general characteristics of the assistive product that describes its appearance and components.
1.4 General features	Single use absorbent products generally comprise: A **Topsheet** which lies against the wearer's skin. It is made from a water-permeable material that allows urine to pass readily through to the absorbent core beneath. An **Acquisition layer** which lies between the topsheet (above) and the absorbent core (below). It is designed to allow urine to enter the pad readily, and spread it over a large area of absorbent core. It does not, itself, absorb urine An **Absorbent core** where urine is captured, spread and stored. It is made from (a) material(s) which absorb(s) and spreads urine readily and retains it under pressure. A **Backsheet** which is a layer of water-proof material which forms the outside surface of the pad, away from the wearer's body. It may be breathable. A **Fastening system** (all-in-one pads only) self-adhesive or hook and loop tabs to fixate the products if a separate supporting product (e.g. underwear or fixation pant) is not used.
Purpose of 1.5	Refers to product models that are included in the specific APS.
1.5 Inclusion	Single use, absorbent products to be used by the person with urinary and/or faecal incontinence with moderate or heavy urine loss
Purpose of 1.6	Refers to product models that are excluded in the specific APS.

1.6 Exclusion	• Washable products • Single use absorbent products for low urine loss • Single use absorbent products that meet the needs of specific patient groups (but are not suitable for widespread use) and are generally more expensive. • Products which capture urine in a bag or receptacle (e.g. urinary catheter or sheath drainage system.) • Digital/technical products (e.g. sensors)
Purpose of 1.7	Important, searchable words that relate to the specific assistive product.
1.7 Keywords	Absorbent products, pads, single use, incontinence

2. Product requirements

The purpose of this section is to provide details of all applicable requirements relative to the specific assistive product. A requirement is mandatory and typically describes what a product should be able to do, how it should appear (product and packaging) etc. Only supply and service requirements considered applicable in procurement of single-use absorbent products.

2.1 Functional requirements

Purpose of 2.1		A functional requirement refers to technical details and other specific functionality that define what a product variation is supposed to accomplish. Per product variation, the requirement should describe the typical user, specific characteristics of the product (in addition to the general features above) as well as the requirements for standard configuration of the product. It is important to focus on performance requirements rather than form factors. It is important to have a clear and specific description of the typical users including e.g. health condition, functional limitation or demographics (range of age, body weight, height, etc.). If applicable, specific context of use (e.g. indoor/outdoor, in noisy environment, etc.) should be specified in the product variations.		
Item	**Product variations**	**Typical user**	**Specific characteristics**	**Requirements for standard configuration**
1	**Single use absorbent system**			
1a	Single use pads (insert) for urine and faeces that are held in place with user's own closely fitting underwear or fixation underwear (1st part of 2-piece system).	Adult or child with moderate or heavy urine loss and/or any faeces. Independent user (able to change product without help from carer) or dependent user with carer(s).	Use in conjunction with user's closely fitting underwear or fixation underwear.	**Pad sizes:** Small, Medium and Large (and ideally XS & XL) **Absorption capacity** Moderate to heavy absorption capacity
1b	Fixation underwear designed to hold pad in position (2nd part of 2-piece system).	User of pads for urine and faeces (1a) (to secure pad in place).	Use in conjunction with single use insert pads (1a).	**Pant (underwear) sizes:** Small, Medium and Large (and ideally XS & XL) **Washable** Minimum 20 times in 60 degrees centigrade without bleaching agents Free from latex and natural rubber

2	Single-use diaper style pads for absorbing urine and/or containing any faeces, with built-in fastener system.	Adult or child with moderate or heavy loss of urine and/or any faeces. Most suitable for dependent users with carer(s) but may be used by independent users. Special recommendation: heavy urine loss and/or loose stool (diarrhoea)	Utilises built-in fastening system (e.g. tapes & tape landing zone, hooks) Includes elastication around legs.	**Size:** Small, Medium and Large (and ideally XS & XL) to fit equivalent body sizes. **Absorption capacity** Moderate to high absorption capacity

Purpose of 2.2	Brief and clear description of general product performance requirements and overall qualities (e.g. stability, strength, durability, waterproof, etc.).
2.2 General design requirements	Zero or minimal leakage when used as intended. Made from non-irritant materials that help maintain healthy skin.
Purpose of 2.3	Details of existing or in-progress national or international standards should be provided here, whether freely or commercially available.
2.3 Standards	There are no essential standards for these products. Absorbent incontinence products are classified as medical devices. Most available standards are generic to medical devices and /or relate to manufacturing and evaluation. The standard relevant to incontinence products has been categorized as NON-ESSENTIAL. Even those standards that are specific to incontinence products may not be about performance quality and do not facilitate a pass or fail assessment although they may allow comparisons between products which may be useful when evaluating cost benefit. These have been classified as DESIRABLE. DESIRABLE STANDARDS: Product standards for single use absorbing products: • ISO 11948-1:1996 Urine-absorbing aids- Part 1: whole-product testing (total absorption capacity) Product standards for fixation pants: • Bursting Strength (D3787, ASTM method) • Crotch Strength (D1424-83, ASTM method) NON-ESSENTIAL STANDARDS: ○ ISO-15621:2017 – Absorbent incontinence aids for urine and/or faeces – General guidelines on evaluation All documentation should be provided in the official language or in English (other languages could be specified too).
Purpose of 2.4	A certificate of conformity confirms that a product conforms to applicable national and/or international regulations. If a certificate is required for the specific assistive product, this information should be requested, e.g., CE (Europe), COC (Japan), GCC (USA).

2.4 Certificate of conformity	As there are no essential standards a certificate of conformity may not be required. However, where standards have been applied, a certificate that the product conforms with that standard should be provided; for example, a declaration of conformity with the medical device directive or the medical device regulation of the European Union. If a certificate of conformity is being provided it should specify the product, all applied standards and the name and contact information of the supplier. The certificate of conformity is a legal document and should be signed by an authorized person at the supplier. The certificate of conformity should be supplied in the official language or in English. (Other languages could be specified too.)
Purpose of 2.5	Lists the relevant scope of information required to identify the appropriate size and weight of the assistive product in its standard configuration (specific dimensions may be given if appropriate).
2.5 Size and weight	Minimum 3 sizes e.g. Small, Medium and Large sizes (XXS, XS, XL, XXL optional).
Purpose of 2.6	Lists the relevant scope of information that should be provided to service providers (e.g. how to select, assemble, fit, adapt, follow up, maintain, repair, refurbish the assistive product). The desired language(s) in which the technical information should be provided should be stated.
2.6 Technical information (for service providers)	Web-based and/or paper-based information about selecting and using absorbent incontinence products should be provided to trained health or social care professionals or another delegated person who has received training following an assessment of an individual's needs.
Purpose of 2.7	Lists the scope of information, and its format, that should be provided to end-users to show how to safely use the assistive product.
2.7 Instructions for use	Guidance for use should be provided on the packaging and be adhered to.
Purpose of 2.8	Refers to the various weather and other environmental conditions, e.g., temperatures, humidity, rain, snow, sunshine, that the assistive product should be able to withstand.
2.8 Environment of use	Not applicable in this call for tender.
Purpose of 2.9	Refers to the duration of the warranty period and the details of the warranty the manufacturer/supplier should provide within the specified period.
2.9 Warranty	Warranty is not applicable to single-use absorbent products. However, the supplier should cover all transport expenses when replacing faulty batches. Following a written complaint, the supplier should investigate and see to the reasonable replacement of the products as soon as possible.
Purpose of 2.10	Refers to the expected duration, in years, of the assistive product. Documents describing how this is ensured must be provided.
2.10 Lifespan	If fulfilled the storage conditions stated in section 2.11 Packaging and labelling, the products should function fully up to 3 years after the production date.
Purpose of 2.11	Lists the scope of information required in packaging and labeling the assistive product. Explains the state of assembly the assistive product should be in when received by the end-user.
2.11 Packaging, labelling, and state of assembly	Products should be packed, transported and stored in such a way that they are not compromised. Incontinence absorbent products should be stored and protected from the extremes of temperature, from weather and humidity and from electro-magnetic radiation during transport and storage.
Purpose of 2.12	Refers to additional product requirements, depending on the specific assistive product, e.g., material, corrosion-resistance, adjustability, foldability, etc.

2.12 Other product requirements	Not applicable in this call for tender.

3. Supply and service requirements

From the information provided below, only those supply and service requirements considered applicable may be used in a procurement bid.

The purpose of this section is to describe key supply and service requirements that are needed in order to ensure that the assistive product is received in due time, operational, being maintained/repaired and refurbished.	
Purpose of 3.1	Lists the scope of information to be requested on how the assistive product will be transported to the place of delivery.
3.1 Transportation	Information on how the product will be transported should be provided and who should pay for the transportation
Purpose of 3.2	Specifies the time between placing an order and receiving delivery of the assistive product (e.g. that it should not exceed 30 calendar days).
3.2 Delivery time	Delivery time can vary according to the order size, inventory of the supplier and manufacturing lead time. For international delivery it can be affected by shipment method and the customs clearance procedures. The delivery time should be agreed by the supplier and customer. In general, after the confirmation of order and payment arrangement, the delivery for domestic order should not exceed 30 working days and the delivery for international order should not to exceed 60 working days.
Purpose of 3.3	Refers to the specific details of the various accessories and spare parts available for the assistive product, including pricing and availability.
3.3 Accessories and spare parts	Not applicable in this call for tender.
Purpose of 3.4	Provides information regarding required maintenance services the supplier will provide, including the timeframe and frequency.
3.4 Maintenance	Not appli. cable in this call for tender.
Purpose of 3.5	Provides information regarding required repairment services the supplier will provide, including the timeframe and frequency.
3.5 Repair	Not applicable in this call for tender.
Purpose of 3.6	Provides information regarding required refurbishment services the supplier will provide, including the timeframe and frequency.
3.6 Refurbishing	Not applicable in this call for tender.
Purpose of 3.7	Specifies if training service providers is required by suppliers, and the key elements included in the training (e.g. selection, assembly, fit, maintenance and repair of the assistive product). Refers to detailed training contents or materials, if available and applicable.
3.7 Training of service providers	Information on how to select and use (including fitting) the most appropriate absorbent product, and how to maintain or restore continence or manage incontinence should be provided.
Purpose of 3.8	Specifies if training users is required by suppliers, and the key elements included in the training (e.g. training to users should include fit, use, maintenance and cleaning of the assistive product). Refers to detailed training contents or materials, if available and applicable.
3.8 Training of users	Information on how to select and use (including fitting) the most appropriate absorbent product type, and how to maintain or restore continence or manage incontinence should be provided.
Purpose of 3.9	Provides information regarding other supply and service requirements.

3.9 Other supply and service requirements	Not applicable in this call for tender.