



# ASSISTIVE PRODUCT SPECIFICATION FOR PROCUREMENT

## Therapeutic footwear

### Objective:

The objective of this specification is to help organizations in procuring good quality therapeutic footwear for diabetic/neuropathic at-risk feet that will be safe to use, which will enhance mobility, increase productivity and prevent secondary problems in daily life for the majority of users.

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	Therapeutic footwear
Purpose of 1.2	As per ISO 9999 classification and terminology document (refer <a href="https://www.iso.org/standard/60547.html">https://www.iso.org/standard/60547.html</a> ).
1.2 ISO 9999 code	09 03 42 Shoes and boots Included are, e.g. shoes for dedicated use, like sport shoes and inlays.  09 06 21 Assistive products for heel protection, toe protection or foot protection.
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	Neuropathic/Diabetic therapeutic footwear (for at risk feet) to offload problem areas, and to prevent secondary problems that may lead to amputation.
Purpose of 1.4	Refers to general characteristics of the assistive product that describes its appearance and components.
1.4 General features	Shoes or sandals with a removable insole to add an extra depth to the footwear or allow custom made insoles. They usually have adjustable closures that ensure a snug fitting upper to hold the foot in place on the innersole to prevent friction/shear forces on the skin, wide and deep toe boxes, wide heel base, cuff around the ankle with rolled seams to prevent friction, built-in forefoot rocker, rocker bottom soles and adjustable straps or shoelaces.
Purpose of 1.5	Refers to product models that are included in the specific APS.
1.5 Inclusion	Prefabricated shoes or sandals with a removable insole or allow custom made insoles to contain deformed feet or at-risk feet.
Purpose of 1.6	Refers to product models that are excluded in the specific APS.
1.6 Exclusion	Custom made orthopedic shoes or sandals.
Purpose of 1.7	Important, searchable words that relate to the specific assistive product.
1.7 Keywords	Therapeutic, diabetic, neuropathic footwear

## 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 therapeutic footwear for diabetic/neuropathic at-risk feet.

### 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
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		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	Therapeutic footwear	Adults and children with diabetic/neuropathic at-risk feet and/or foot/ankle deformities who need shoes that protect, maintain feet structure and have ulcer closure.	<p><u>Shapes:</u> different shapes could include, but not limited to, broad deep toe boxes, wide in the midfoot, inflated and outflared as well as be accommodative for an extra depth shoe that will allow the insertion of an orthotic/insole.</p> <p><u>Upper design:</u> multiple designs and colors for both men and women that are acceptable and appropriate for specific region, country, community.</p> <p><u>Types of closure:</u> Suggested closures include laces, velcro, buckles or a combination</p> <p><u>Heel design:</u> A wide heel base that ensure medial and lateral stability is essential. The heel can be both close type with heel counter or adjustable wide and secure back-strap type.</p> <p><u>Toe design:</u> Covered toe design to prevent trauma/injury to forefoot area. Opened toe design or with closed toe box for hotter climates. Vamp/tongue of the shoe or sandal allow opening the shoe up to the metatarsals to facilitate easy donning and doffing.</p>	<p><u>Sizes:</u> In US shoe sizing</p> <ul style="list-style-type: none"> <li>• Women sizes 5-12</li> <li>• Men's sizes 6-13</li> <li>• European and Japan sizes men's and women's determined by foot length.</li> </ul> <p>Removable insole of at least 5mm in thickness.</p> <p><u>Upper material:</u> Common acceptable materials include leather, fabric, canvas, mesh with reinforced areas over the toes and cupping the heel.</p> <p><u>Insole material:</u> EVA, polyurethane, micro-cellular rubber, rubber. It would be better to have closed cell materials and materials that don't absorb moisture for good foot health.</p> <p><u>Soling material:</u> Materials can include rubber, polyurethane, EVA, leather or comparable properties. All these materials have different properties, but may be more accessible in different regions.</p>
Purpose of 2.2		Brief and clear description of general product performance requirements and overall qualities (e.g. stability, strength, durability, waterproof, etc.).		

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2.2 General design requirements	<p>Footwear must fit the foot properly, fasten snugly to prevent movement of the foot, accommodate the shape of the foot and allow for bony deformities, accommodate orthotics or insoles, while providing support as well as comfort, and easy to do on and do off. Made of materials that are breathable, does not trap moisture, is fast drying, and colours that reflect heat and are applicable to the regions climate and conditions.</p> <p>The cuff or topline around the ankle should be well fitting and with rolled seams to prevent friction/blistering (particularly over the achillis tendon) and can extend over the malleoli to add medial and lateral stability to the ankle if needed.</p> <p>Shoe uppers are easily adjustable for people with low finger dexterity and allow evenly distribute pressure - particularly for swollen feet and minimize friction.</p> <p>Extra depth to allow for the insertion of custom made orthotics/insoles. Provides good heel control to ensure medial and lateral stability.</p> <p>Insoles should redistribute pressure and provide support and cushioning. Made of materials that are durable, moldable, and washable.</p> <p>The outsole should have built-in forefoot rocker sole or at least toe-spring to assist in toe off and should be made of a durable and light weight rubber composite that can withstand high traffic on rough terrain and can easily be repaired with adhesives.</p> <p>Soling materials are durable, light weight and provide support and control/traction for daily activity, particularly in cognizance of high traffic in rural areas.</p>
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	Sizing varies from country to country, but there are fitting standards that can be applied to the correct fitting of shoes, universally. Footwear sizing standards are not established or enforced universally. It would be important for people selling or evaluating shoe quality and fit be appropriately trained, especially when shoes are being used for therapeutic purposes.
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).

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2.4 Certificate of conformity	<p>A certificate that the product conform with applicable national or international regulations and standards should be provided (for example, a declaration of conformity with the medical device directive or the medical device regulation of the European Union).</p> <p>If the product does not conform with applicable national or international regulations and standards, the supplier should provide a certificate that the product comply with the requirements in this call for tender and is safe and effective for use by the typical user.</p> <p>The certificate should specify the product, all applied standards, if any, and the name and contact information of the supplier and be provided with the tender. The certificate of conformity is a legal document and must be signed by an authorized person at the supplier.</p> <p>The certificate of conformity should be supplied in the official language or in English (other languages could be specified too).</p>
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	There are multiple sizes, widths and even shapes available for footwear. Many of these options vary from country to country. Sometimes even custom made for severely deformed feet. The weight should be light but stable and durable.
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)	Information on materials of upper shoes/sandals, insole and outsole, weight, sizes, applicable pathology should be provided. Further information on assessment of users' need for selection of proper therapeutic footwear and follow-up can be provided as well.
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	<p>Information should be provided to users on the proper fit and the correct home care of shoes to ensure continued comfort and longevity. Instructions should be provided to users on how to:</p> <ul style="list-style-type: none"> <li>• properly fit the footwear initially</li> <li>• check the fit of the shoes each time doffing is completed</li> <li>• do daily overall foot skin checks</li> <li>• notice repairs or replacements are needed</li> <li>• (when to) discontinue use should there be an indication of the shoes causing pressure/ friction</li> <li>• immediately get in touch with the service provider that fitted the shoes should any problems occur</li> </ul>
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	<p>Footwear is available for a multitude of environments, hot, cold, dry, wet and very humid conditions. In different situations closed footwear or sandals, may be called for. Shoes/boots may be needed, or shoes that are more porous/breathable, depending on weather conditions. Environment can dictate types of footwear.</p>
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.

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2.9 Warranty	Not applicable in this call for tender.
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	Lifespan is very hard to predict, it depends on environmental conditions, use, size/weight of the person and even deformity that may be present.
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	<i>Packaging should include cleaning instructions/wash labels.</i>
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 footwear 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	A turnaround delivery time of 21 days is recommended in order to ensure continuum of care for patients.
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	<p><b>Please select the applicable option:</b></p> <p><input type="checkbox"/> Not applicable in this call for tender</p> <p><input type="checkbox"/> Information about types of treatments (e.g. oils and silicone to many of the upper materials), payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several maintenance jobs are done on the same route; hotel bills; in cases the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)</p>
Purpose of 3.5	Provides information regarding required repairment services the supplier will provide, including the timeframe and frequency.

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3.5 Repair	<p><b>Please select the applicable option:</b></p> <p><input type="checkbox"/> Not applicable in this call for tender</p> <p><input type="checkbox"/> Information about types of repairs (e.g. new closures, replacement soles/heels), payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several repair jobs are done on the same route; hotel bills; in cases the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)</p>
Purpose of 3.6	Provides information regarding required refurbishment services the supplier will provide, including the timeframe and frequency.
3.6 Refurbishing	<p><b>Please select the applicable option:</b></p> <p><input type="checkbox"/> Not applicable in this call for tender.</p> <p><input type="checkbox"/> Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several refurbishing jobs are done on the same route; hotel bills; In cases the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided).</p>
Purpose of 3.7	Specifies if training to service providers is required, who will be trained and the training provided by suppliers. Indicate key elements included in the training (e.g. selection, assembly, fit, maintainance and repair of the assistive product). Refer to detailed training contents or materials, if available and applicable.
3.7 Training of service providers	<p><b>Please select the applicable option:</b></p> <p><input type="checkbox"/> Not applicable in this call for tender.</p> <p><input type="checkbox"/> Information about assessing, fitting, when to follow-up, repair, and replace the footwear should be provided to the appropriate service provider. Assessing, fitting, demonstrating and training in the use and follow up of the footwears should be done by the appropriately trained personnel. Basic advice as well as individual assessment and rehabilitation intervention is often necessary, in addition to the footwear.</p>
Purpose of 3.8	Specifies if training to users is required and the training to be provided by suppliers to users. Indicate key elements included in the training (e.g. training to users should include fit, use, maintenance and cleaning of the assistive product). Refer to detailed training contents or materials, if available and applicable.
3.8 Training of users	<p><b>Please select the applicable option:</b></p> <p><input type="checkbox"/> Not applicable in this call for tender.</p> <p><input type="checkbox"/> Basic training should include how to check shoe fit, how to complete overall foot skin checks, how to notice when repairs or replacements are needed, when to discontinue use, and how to contact the appropriately trained service providers when needed. Training should include checking fit of the footwear each time doffing is completed.</p>
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.