Objective:

The objective of this specification is to help organizations in procuring good quality spectacles for near tasks that are durable and which help individuals with visual impairment in performing their near tasks comfortably.

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.

<table>
<thead>
<tr>
<th>Purpose of 1.1</th>
<th>Name of product as per WHO priority APL and/or commonly used names.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Name of product</td>
<td>Spectacles, low vision and short distance</td>
</tr>
<tr>
<td>Purpose of 1.2</td>
<td>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>).</td>
</tr>
<tr>
<td>1.2 ISO 9999 code</td>
<td>22 03 06 Spectacles and contact lenses</td>
</tr>
<tr>
<td>Devices which enable a person to focus her/his vision Included are, e.g. contact lens care products.</td>
<td></td>
</tr>
<tr>
<td>Purpose of 1.3</td>
<td>Describes the product type in clear, simple, easily understood language and the intended use in addressing functional needs.</td>
</tr>
<tr>
<td>1.3 Description and intended use</td>
<td>Plus powered lenses that are mounted onto the spectacle frame to focus the image to help individuals with visual impairment because of uncorrected refractive error and/or presbyopia to perform their near tasks (e.g. reading) comfortably. They are available in various powers and designs.</td>
</tr>
<tr>
<td>Purpose of 1.4</td>
<td>Refers to general characteristics of the assistive product that describes its appearance and components.</td>
</tr>
<tr>
<td>1.4 General features</td>
<td>Scratch- and impact-resistant plus powered lenses mounted in a spectacle frame. Reading glasses can start from low-powered range of 0.50D near addition and is generally available up to a near addition power of +4.00D. This can be incorporated either in the bifocals, progressive addition lenses or prescribed as separate reading glasses. However, once the power is more than +4.00D, it is generally referred to as spectacle magnifiers. Base-in prisms are available from +5.00D to +12.00D in spectacle magnifiers. The availability of the spectacle magnifiers (without base-in prisms) is up to +44D. However, considering the extremely short working distance that a person will be working at, usually spectacle magnifiers up to +24D can be prescribed for comfortable near work.</td>
</tr>
<tr>
<td>Purpose of 1.5</td>
<td>Refers to product models that are included in the specific APS.</td>
</tr>
<tr>
<td>1.5 Inclusion</td>
<td>Near vision spectacles ranging from +0.50D to +4D, full-field and half-eye frames. Spectacle magnifiers ranging from +4D to +44D.</td>
</tr>
<tr>
<td>Purpose of 1.6</td>
<td>Refers to product models that are excluded in the specific APS.</td>
</tr>
<tr>
<td>1.6 Exclusion</td>
<td>Far vision spectacles, full-field and half-eye frames.</td>
</tr>
<tr>
<td>Purpose of 1.7</td>
<td>Important, searchable words that relate to the specific assistive product.</td>
</tr>
<tr>
<td>1.7 Keywords</td>
<td>Visual impairment, reading, writing, spectacle magnifier, near addition</td>
</tr>
</tbody>
</table>

2. Product requirements

2.1 Functional 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 spectacles/spectacle magnifiers for low vision and short distance.
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.

<table>
<thead>
<tr>
<th>Item</th>
<th>Product variations</th>
<th>Typical user</th>
<th>Specific characteristics</th>
<th>Requirements for standard configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Near-vision ready-to-wear spectacles</td>
<td>Individuals with presbyopia needing positive powered lenses to perform prolonged reading, writing and other near vision tasks</td>
<td>Range: +0.50D to +4D Full-field and half-eye frames</td>
<td>Solar UV transmission: for solar UVB transmittance &lt;5%, for solar UVB transmittance calculated up to 400 nm &lt; 50%</td>
</tr>
<tr>
<td>2</td>
<td>Spectacle magnifiers</td>
<td>Individuals with visual impairments who cannot read or see near targets clearly to perform prolonged reading and writing tasks. These are specifically for patients who are binocular, to aid them for their high convergence demand due to the high-powered plus lenses.</td>
<td>Range: +4D to +44D</td>
<td>Solar UV transmission: for solar UVB transmittance &lt;5%, for solar UVB transmittance calculated up to 400 nm &lt; 50% Single vision lens - Range: 4D to 20D Single vision lens with prismatic power for binocular viewing – Range: 4D to 10D. High power Hyperoculars – Range 8D to 44D.</td>
</tr>
</tbody>
</table>

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

The spectacle/spectacle magnifiers should be durable and light weight. Lens diameter vary with the lens design and frame size of the spectacles. Lens design preferably to be aspheric for better image quality without spherical aberrations.

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

All documentation should be in the official language or in English (other languages could be specified too).

Current product standards for spectacle magnifiers:
Several international standards exist for testing and requirements for spectacles, see publications issued by ISO/TC 172 SC 7https://www.iso.org/committee/53738/x/catalogue/p/1/u/0/w/0/d/0
For example:
ISO 15253: 2000 Ophthalmic optics and instruments - Optical devices for enhancing low vision
ISO 16034:2002 Ophthalmic optics — Specifications for single-vision ready-to-wear near-vision spectacles,
EN 14139:2002 Ophthalmic optics — Specifications for single-vision ready-to-wear near-vision spectacles
### 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

A certificate that the product conforms 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).

If the product does not conform with applicable national or international regulations and standards, the supplier should provide a certificate that the product complies with the requirements in this call for tender and is safe and effective for use by the typical user.

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 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

Information about the lens type, material, coating, frame size, frame material should be provided.

### 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

Instructions on how to assemble, adapt, maintain, service, and repair the spectacles and spectacle magnifiers should be provided. The technical information should be provided in the official language or in English (other languages could be specified too).

### 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

A user manual containing information on how to use and care for the lens and frame of the spectacles/spectacle magnifiers should be provided. It should provide instructions on how to safely and effectively adapt, maintain, and clean the product. It is intended for the user and/or caregiver.

The user manual may be provided in print or electronic format. The user manual should be provided in the official language, and if applicable, in English (other languages could be specified too).

### 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

It is recommended to keep the spectacles/spectacle magnifiers away from excessive temperature. Spectacles/spectacle magnifiers can generally be used in temperatures up to 50°C and as low as -30°C.

### 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

Provided normal heedful use, the supplier should, during the warranty period and without extra expenses, rectify faults arising in connection with manufacturing and/or material errors. This comprises all spare parts and labour, except for normal wear and tear of the product.
| **Purpose of 2.10** | 
|---|---|
| **2.10 Lifespan** | Under normal conditions of use, the spectacle/spectacle magnifier should be designed for at least 5 years of use. |
| **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** | Each spectacle/spectacle magnifier should be delivered in an individual package with a label clearly stating details of the product (e.g. information about the lens type, material, coating, temple design, frame size, temple size, bridge size etc. should be provided). All necessary parts should be included in the package and the product should be delivered to the end-user fully assembled. The package should withstand handling during transport. If any special tools are required, it should be included with the delivery. |
| **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** | In the tender, the supplier should provide the following information about the spectacles/spectacle magnifiers: |
| &bull; Lens type
| &bull; Lens material
| &bull; Lens coating
| &bull; Power of the lens
| &bull; Frame size
| &bull; Bridge size
| &bull; Optical centration distance
| &bull; Company code |

### 3. Supply and service requirements

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

<table>
<thead>
<tr>
<th><strong>Purpose of 3.1</strong></th>
<th>Lists the scope of information to be requested on how the assistive product will be transported to the place of delivery.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3.1 Transportation</strong></td>
<td>Information on how the spectacles/spectacle magnifiers will be transported should be provided and who should pay for the transportation.</td>
</tr>
<tr>
<td><strong>Purpose of 3.2</strong></td>
<td>Specifies the time between placing an order and receiving delivery of the assistive product (e.g. that it should not exceed 30 calendar days).</td>
</tr>
<tr>
<td><strong>3.2 Delivery time</strong></td>
<td>The time between placing an order of up to 100 spectacles/spectacle magnifiers and receiving delivery of them should not exceed 30 working days.</td>
</tr>
<tr>
<td><strong>Purpose of 3.3</strong></td>
<td>Refers to the specific details of the various accessories and spare parts available for the assistive product, including pricing and availability.</td>
</tr>
</tbody>
</table>
### 3.3 Accessories and spare parts

The supplier should offer the following accessories:
- Box/case/pouches
- Velvet cleaning cloth

No spare parts are included.

All parts that the spectacles/spectacle magnifiers consist of, and which may be replaced at some stage, should be offered as spare parts. The supplier should state which variations of spectacles/spectacle magnifiers the accessories and spare parts are meant for. When an accessory consists of one part, the same part should not be offered both as an accessory and a spare part, but only as an accessory. When an accessory consists of several parts that can be replaced, all replaceable parts should be offered as spare parts. Spare parts should be made available for a period of at least 5 years after the last order of spectacles/spectacle magnifiers. The price of the spare parts should be offered per part and not per set or pair.

### Purpose of 3.4

Provides information regarding required maintenance services the supplier will provide, including the timeframe and frequency.

### 3.4 Maintenance

Information about 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; who should provide the spare parts; 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.)

### Purpose of 3.5

Provides information regarding required repairment services the supplier will provide, including the timeframe and frequency.

### 3.5 Repair

Information about 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; who should provide the spare parts; 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.)

### Purpose of 3.6

Provides information regarding required refurbishment services the supplier will provide, including the timeframe and frequency.

### 3.6 Refurbishing

Information about 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; who should provide the spare parts; 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.)

### 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 about assembling, fitting, maintaining, and repairing the spectacles/spectacle magnifiers should be provided to the service provider.

### 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 about using and maintaining the spectacles/spectacle magnifiers should be provided to the end-user.

### Purpose of 3.9

Provides information regarding other supply and service requirements.

### 3.9 Other supply

Not applicable in this call for tender.
| and service requirements |   |