

**Annex – 6**  
**Technical Specifications**

Table of contents:

1. Item No.1.....	p.2-3
2. Item No.2.....	p.3-4
3. Item No.3.....	p.4-5
4. Item No.4.....	p.5-6
5. Item No.5.....	p.6-7
6. Item No.6.....	p.7-9
7. Item No.7.....	p.9-10
8. Item No.8.....	p.10-11
9. Item No.9.....	p.11-12
10. Item No.10.....	p.12-13
11. Item No.11.....	p.13-14
12. Item No.12.....	p.14-15
13. Item No.13.....	p.15-16
14. Item No.14.....	p.17-18

1. Autoclave	Quantity, pcs:
<p><b>Product Description</b> Stand-alone table top steam sterilizer with drying cycle. Autoclaves are also known as steam sterilizers, and are typically used for healthcare or industrial applications. An autoclave is a machine that uses steam under pressure to kill harmful bacteria, viruses, fungi, and spores on items that are placed inside a pressure vessel.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50 Hz., with voltage surge protection.</li> <li>• Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• With automatic control of the sterilization cycle, automatic discharge of cold air, and automatic discharge of steam at the end of the cycle.</li> <li>• Control panel: working status indicator and permanent monitoring of pressure, temperature and cycle stages.</li> <li>• Safe protection of water lacking</li> <li>• Protection against over temperature and overpressure</li> <li>• Audio visual alarm at least for: end of cycle, failure or potential danger and standby mode.</li> <li>• Fully stainless steel structure.</li> <li>• Single door, self-sealing with high-quality silicone gasket</li> <li>• Equipped with four (4) antistatic castors, for easy mobility, and at least two of them with brakes.</li> <li>• Program control unit for fully automated process control</li> <li>• Adjustable working temperature at least up to: 134°C.</li> <li>• Heat average <math>\leq \pm 1^\circ\text{C}</math></li> <li>• Timer scope at least: 60 min</li> <li>• Max working pressure: 0,23 MPa.</li> <li>• Capacity at least: 50 liters.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>• 2 (two) stainless steel sterilization baskets.</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product, even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	50
<p><b>Documentation required:</b> Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b> Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p>	

<ul style="list-style-type: none"> <li>Valid manufacturing licenses.</li> <li>And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIa devices, or</li> <li>FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>IEC 61010-2-040 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials.</li> <li>IEC 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 1: General requirements.</li> </ul> </li> </ul>	
<p><b>2. Blood collection mixer</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b>  The electric blood collection mixer is designed to measure and shake the blood bag during a blood collection to avoid clot meanwhile is mixed with anticoagulant fluid in the bag.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50 Hz.</li> <li>Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>Capable of working with all types of blood collection bags</li> <li>Constant and uniform mixing of blood.</li> <li>Automatic tare for empty bag.</li> <li>Automatic tube clamping at the end of collection</li> <li>Adjustable high and low flow alarms</li> <li>Default value setting (routine value) in ml</li> <li>Real-time display of blood volume</li> <li>Setting of desired volume to collect at any time, even during collection.</li> <li>Collection Volume: at least 1000 ml</li> <li>Optical and visual end of collection alarm.</li> <li>Mixer tray detachable to better clean.</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product, even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	<p>40</p>
<p><b>Documentation required:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>Manufacturer brochure or data sheet including at least all technical specifications required.</li> </ul>	

<ul style="list-style-type: none"> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p>Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>• Valid manufacturing licenses</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with directive 93/42 EC or regulation 2017/745 for Class I devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>o IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>o IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.</li> </ul> </li> </ul>	
<p><b>3. Blood bag tube sealer</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b>  Blood bag tube sealer is a Heat Sealer specifically designed for sealing blood bag tubes.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50 Hz.</li> <li>• Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Bench-top device with fixed sealing head and hand-held sealing unit.</li> <li>• Radiofrequency sealer.</li> <li>• Sealer for polyvinyl chloride (PVC) and ethylene vinyl acetate (EVA) lines of different diameters.</li> <li>• Capacity at least 1500 stamps per load.</li> <li>• Operation indicator light.</li> <li>• Sealing, joining, with slit or cutting line for later segmentation.</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product, even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	<p>20</p>
<p><b>Documentation required:</b></p>	

<p>Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b> Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>• Valid manufacturing licenses</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with directive 93/42 EC or regulation 2017/745 for Class I devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b> Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>o IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>o IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.</li> </ul> </li> </ul>	
<p><b>4. Blood Bag Tube Stripper</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b> The blood bag tube stripper is designed to strip undiluted blood from the donor tubing.</p> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Roller clamp, for manual use, specifically designed to peel, seal and cut the PVC line, mechanically.</li> <li>• Body material: Stainless steel or high quality aluminum alloy.</li> <li>• Handles covered in non-slip material, which improves grip for the operator.</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product, even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	<p>20</p>
<p><b>Documentation required:</b> Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> </ul>	

<ul style="list-style-type: none"> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b> Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>• Valid manufacturing licenses</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with directive 93/42 EC or regulation 2017/745 for Class I devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b> Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes or</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 with the international safety &amp; regulatory standards that the product fulfills.</li> </ul>	
<p><b>5. Benchtop Centrifuge</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b> A benchtop centrifuge is An electrically-powered device intended to be used to separate the components of various types of clinical specimens using centrifugal force, either alone or after addition of reagents or other additives, for subsequent in vitro diagnostic analysis.</p> <p>The Centrifuge is used</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50/60 Hz.</li> <li>• Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Tabletop centrifuge for processing blood collection tubes and urine tubes.</li> <li>• Built-in digital tachometer.</li> <li>• Rotor with the following features: <ul style="list-style-type: none"> <li>o Swing-out rotor.</li> <li>o At least 10 positions for tubes.</li> <li>o Máx. capacity of each tube: between 10 ml and 15 ml.</li> <li>o Autoclavable.</li> </ul> </li> <li>• With the possibility of exchanging the tube-holder head.</li> <li>• Electronic speed and time regulator</li> <li>• Start and stop indicator.</li> <li>• LCD display that shows the speed and spin time parameters.</li> <li>• Speed range: at least between 0 to 4000 rpm.</li> <li>• Airtight and easy-to-clean centrifugation chamber.</li> </ul>	<p>20</p>

<ul style="list-style-type: none"> <li>• Lid with safety lock until complete stop and design to prevent the emission of bioaerosols.</li> <li>• Anti-spill system.</li> <li>• Asynchronous motor (without brushes; maintenance-free), mounted on a shock absorber system.</li> <li>• Noise level &lt; than 60 dBA.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>• 1 (one) additional rotor for tubes as detailed above.</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product, even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	
<p><b>Documentation required:</b> Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b> Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>• Valid manufacturing licenses</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE),</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b> Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (desirable) or</li> <li>• Valid ISO 9001 Quality Management Systems - Requirements.</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>o IEC 61010-2-020 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges.</li> <li>o EN 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.</li> <li>o EN 61326-1 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.</li> </ul> </li> </ul>	
<p><b>6. Laboratory Oven</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b> Forced-air laboratory oven is a device with a heating chamber designed to provide fan-assisted convection to ensure a homogenous temperature profile in</p>	<p>20</p>

<p>the chamber. It is used for laboratory procedures that involve drying, heating, and sterilizing objects.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50/60 Hz.</li> <li>• Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Forced convection type</li> <li>• Stainless steel (AISI 304 or better) chamber material</li> <li>• Tabletop configuration</li> <li>• Temperature range: <ul style="list-style-type: none"> <li>o Max: at least 250°C</li> <li>o Min: at least 40°C</li> </ul> </li> <li>• Capacity: approx. 58 liters</li> <li>• Entry port at least Ø 20 mm</li> <li>• Internal Lighting</li> <li>• Number of door(s): 1</li> <li>• With at least 2 shelves with adjustable positions.</li> <li>• Maximum load: at least 25 kg on each shelf.</li> <li>• Overheating alarms and programmed time elapsed</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	
<p><b>Documentation required:</b></p> <p>Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b></p> <p>Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>• Valid manufacturing licenses.</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (desirable) or</li> <li>• Valid ISO 9001 Quality Management Systems - Requirements.</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards:</li> </ul>	



<ul style="list-style-type: none"> <li>o EN 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.</li> <li>o EN 61326-1: Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.</li> <li>o DIN 12880 Electrical laboratory devices - Heating ovens and incubators.</li> </ul>	
<b>7. Water bath</b>	<b>Quantity, pcs:</b>
<p><b>Product Description</b>  The thermostatic water bath is used to incubate samples in water at a constant temperature for a long period of time.  Applications include heating reagents, melting substrates, or incubating cell cultures.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50/60 Hz.</li> <li>• Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Capacity: at least 10L.</li> <li>• Temperature range: 36 ° C - 100 ° C.</li> <li>• Temperature accuracy: <math>\leq \pm 1^{\circ}\text{C}</math>,</li> <li>• Time range: at least 0~999 min.</li> <li>• Safety thermostat protection against over temperature or lack of liquid.</li> <li>• With audible alarm and high temperature cut-off.</li> <li>• Visual operation indicator</li> <li>• Heating elements made of stainless steel (AISI 304 or better) resistant to corrosion and high temperature.</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	20
<p><b>Documentation required:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b>  Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>• Valid manufacturing licenses.</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar.</li> </ul> </li> </ul>	

<p><b>Safety &amp; product Standards:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (desirable) or</li> <li>• Valid ISO 9001 Quality Management Systems - Requirements.</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>o EN 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.</li> <li>o EN 61326-1 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.</li> <li>o EN 61010-2-010 Particular requirements for laboratory equipment for the heating of materials.</li> </ul> </li> </ul>	
<p><b>8. Rhesuscope 3 Plates</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b>  The Rhesuscope is used for HR tests, classification and adaptation of blood images, illumination of antiserum transparencies and albumin control.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50 Hz.</li> <li>• Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• 3 work surfaces (3 plates) that can be renewed successively by simply turning them over.</li> <li>• Metal structure protected by oven-baked enamel paint.</li> <li>• Plates with the following features: <ul style="list-style-type: none"> <li>o Material: plastic or white opaline.</li> <li>o Dimensions: at least 160 mm x 300 mm.</li> <li>o Capacity per plate: 80 to 100 agglutinations.</li> </ul> </li> <li>• Heating and lighting <ul style="list-style-type: none"> <li>o Light: white.</li> <li>o Temperature <math>\leq</math> 45°C.</li> </ul> </li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	<p>40</p>
<p><b>Documentation required:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b></p>	

<p>Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>Valid manufacturing licenses.</li> <li>And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>European Certificate of Conformity (CE) or</li> <li>FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (desirable) or</li> <li>Valid ISO 9001 Quality Management Systems - Requirements.</li> </ul>	
<p><b>9. Precision Balance</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b>  Electronic analytical balance is an electronic laboratory instrument designed for weighing with a high degree of accuracy and precision.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50 Hz.</li> <li>Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>Maximum weight: approx. 6000 g</li> <li>Minimum weight: <math>\leq</math> 1g</li> <li>Accuracy: 0.01 g</li> <li>Repeatability: <math>\leq</math> 0.01 g</li> <li>With tare function, which allows automatically subtract the weight of the container or container used to obtain the net weight</li> <li>Digital display</li> <li>Weighing plate with the following features:</li> <li>Material: stainless steel resistant to corrosion.</li> <li>Width / Diameter: approx. 180 mm</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product , even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	<p>20</p>
<p><b>Documentation required:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>Manufacturer authorization Letter.</li> <li>Free Sale Certificate.</li> <li><b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b>  Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>Valid manufacturing licenses.</li> </ul>	

<ul style="list-style-type: none"> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE), or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (desirable) or</li> <li>• Valid ISO 9001 Quality Management Systems - Requirements.</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>o EN 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.</li> <li>o EN 61326-1: Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.</li> </ul> </li> </ul>	
<p><b>10. Orbital Shaker</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b>  Orbital shaker has a horizontal circular shaking motion that ensures uniform sample agitation with platforms that can accommodate different vessels.  For use in blood banks, serology, bacteriology and chemical laboratories, etc.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50 Hz.</li> <li>• Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Electronic adjustment of speed and stirring time.</li> <li>• Digital reading of stirring time and speed.</li> <li>• Adjustable speed in range at least: 50-250 r.p.m..</li> <li>• Timer at least: from 1 min. to 19h 59 minutes.</li> <li>• Amplitude: <math>\geq</math> 15mm.</li> <li>• End of cycle audible alarm.</li> <li>• Non-slip feet,</li> <li>• Platform covered in non-slip material</li> <li>• Easy to clean,</li> <li>• Platform dimensions: with minimum space for 4 Petri dishes.</li> <li>• Load capacity: at least to 2 kg.</li> <li>• Maintenance-free motor</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product, even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	<p>20</p>
<p><b>Documentation required:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> </ul>	

<ul style="list-style-type: none"> <li>● <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b> Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>● Valid manufacturing licenses.</li> <li>● And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>○ European Certificate of Conformity (CE) or</li> <li>○ FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>○ WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b> Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>● Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (desirable) or</li> <li>● Valid ISO 9001 Quality Management Systems - Requirements.</li> <li>● Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the following international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>○ EN 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.</li> <li>○ EN 61326-1 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.</li> <li>○ UNE-EN IEC 61010-2-051 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring</li> </ul> </li> </ul>	
<b>11. Vortex Mixer</b>	<b>Quantity, pcs:</b>
<p><b>Product Description</b> A vortex mixer is a device designed to mix small vials of liquid. It consists of an electric motor with the drive shaft oriented vertically and attached to a cupped rubber piece mounted slightly off-center. As the motor runs the rubber piece oscillates rapidly in a circular motion. When a test tube is pressed into the rubber cup the motion is transmitted to the liquid inside and a vortex is created.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>● Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50 Hz.</li> <li>● Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>● For use on the counter.</li> <li>● With anti-slip feet.</li> <li>● Onetouch system Silicone work surface.</li> <li>● For single tube of different sizes (up to 15 ml)</li> <li>● Orbital diameter: <math>\leq</math> 4.5 mm</li> <li>● Maximum handling volume: approx. 50 ml</li> <li>● Adjustable speed range: approx. between 0 - 3000 r.p.m,</li> <li>● Motor: brushless</li> </ul>	20

<p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product, even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	
<p><b>Documentation required:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b>  Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>• Valid manufacturing licenses.</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (desirable) or</li> <li>• Valid ISO 9001 Quality Management Systems - Requirements.</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>o EN 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.</li> <li>o EN 61326-1 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.</li> <li>o UNE-EN IEC 61010-2-051 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring</li> </ul> </li> </ul>	
<p><b>12. Water Purifier System</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b>  A water purifier system is an electrically-powered device (assembly of one or more components), designed to remove unwanted chemical, particulate, and/or biological contaminants from water. The system purifies water using a combination of methods including particulate filtration, chemical disinfection, deionization, reverse osmosis, and/or ultraviolet light.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50 Hz.</li> <li>• Power cord with “F” type plug according to CHAD standards.</li> <li>• Current consumption less than 20A</li> </ul>	<p>20</p>

<ul style="list-style-type: none"> <li>Any type of special electrical requirement that the equipment demands must be indicated to ensure its correct operation (for example: if it requires a stabilized power supply, special grounding).</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>Electric water purifier with a tank, for laboratory use.</li> <li>Benchtop.</li> <li>Production capacity: at least 2l/h</li> <li>LCD display with status information.</li> <li>With an automatic stop system, when there is no water supply.</li> <li>Work indicator light.</li> <li>Indicate the cooling water consumption per hour</li> <li>Purification methods, at least: <ul style="list-style-type: none"> <li>Pre-filter set</li> <li>Reverse osmosis module</li> <li>Deionization module</li> <li>Final stage polishing module</li> </ul> </li> <li>Recirculation system.</li> <li>Storage tank capacity: approx. 30L for storage Type 2 pure water</li> <li>Water Quality (ASTM OR ISO 3696): ASTM Type 1 ultrapure water and ASTM Type 2 pure water as follow: <ul style="list-style-type: none"> <li>Ultrapure Water Quality ASTM Type 1, at least or better: <ul style="list-style-type: none"> <li>Resistivity (conductivity): 18.2 MΩ x cm (0.055 μS/cm)</li> <li>Total organic carbon (TOC): &lt; 5 ppb</li> <li>Bacterial Content: &lt; 0.001 CFU/ml</li> <li>Endotoxins: &lt; 0.01 EU/ml</li> <li>Particles &gt; 0.22 μm: &lt; 1/ml</li> </ul> </li> <li>Pure Water Quality ASTM Type 2 at least or better:: <ul style="list-style-type: none"> <li>Resistivity (conductivity): 10 MΩ x cm ( 0.1 μS/cm)</li> <li>Total organic carbon (TOC): &lt; 5 ppb</li> <li>Bacterial Content: &lt; 0.01 CFU/m</li> <li>Endotoxins: &lt; 0.01 EU/ml</li> <li>Particles &gt; 0.22 μm: &lt; 1/ml</li> </ul> </li> </ul> </li> <li>Water dispensation: <ul style="list-style-type: none"> <li>Type 1 ultrapure water dispensed through the point-of-use filter on the front panel.</li> <li>Type 2 pure water with a dispensing valve directly from the storage tank.</li> </ul> </li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product, even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	
<p><b>Documentation required:</b></p> <p>Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>Manufacturer authorization Letter.</li> <li>Free Sale Certificate.</li> <li><b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	

<p><b>Regulatory approvals required:</b>  Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>• Valid manufacturing licenses.</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes ( desirable) or</li> <li>• Valid ISO 9001 Quality Management Systems - Requirements.</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>o EN 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.</li> <li>o EN 61326-1 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.</li> <li>o ASTM or ISO 3696 Water for analytical laboratory use — Specification and test methods.</li> </ul> </li> </ul>	
<p><b>13. Multichannel Micropipette, Set x 2</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b>  A micropipette is a precision instrument used to measure and transfer volumes of liquids in the microliter (µL) range.</p> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Set of 2 adjustable multichannel micropipette of 8 channels each.</li> <li>• Operating mode: mechanical</li> <li>• Volume selection from: <ul style="list-style-type: none"> <li>o One (1) micropipette: between 10 to 100 µl</li> <li>o One (1) micropipette: between 100 to 1000 µl</li> </ul> </li> <li>• Volume increment in the range of: 0.01 to 1 µl</li> <li>• Display on the handle to visualize the adjusted delivery volume.</li> <li>• 360° rotating volumetric module.</li> <li>• Sequential tip ejection.</li> <li>• Type of tips: universal pipette tip, preferable.</li> <li>• Indication of color code</li> <li>• Autoclavable: at least lower part.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>• Startup set of tips for each pipette</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product, even if they are not included in these required technical specifications must be included and <b>listed in the offer.</b></i></p>	<p>60</p>
<p><b>Documentation required:</b>  Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> </ul>	



<ul style="list-style-type: none"> <li>• Should include the Calibration report according to ISO 8655 or DIN 12600</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b> Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>• Valid manufacturing licenses.</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with Vitro Diagnostic Medical Devices Regulation 2017/746 or Directive 98/79 EEC and Agreement Letter signed with the NB demonstrating the on-going MDR application, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b> Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>o ISO 8655-2 Piston-operated volumetric apparatus - Part 2: Pipettes</li> </ul> </li> </ul>	
<p><b>14. Digital Blood Pressure Monitor</b></p>	<p><b>Quantity, pcs:</b></p>
<p><b>Product Description</b> A digital blood pressure monitor is an automatic electronic sphygmomanometer non-invasive, designed to non-invasively measure blood pressure, regulating automatically the arm-cuff inflation and measurement cycles.</p> <p><b>Electrical Requirements:</b></p> <ul style="list-style-type: none"> <li>• Rechargeable battery operated.</li> <li>• Power requirements according to CHAD standards: 220 VAC <math>\pm</math> 10%, 50 Hz.</li> <li>• Power cord with “F” type plug according to CHAD standards.</li> </ul> <p><b>Technical specifications:</b></p> <ul style="list-style-type: none"> <li>• Measurement interval, min: User selectable: <math>\geq 5</math></li> <li>• Measurement time (s) <math>\leq 60</math>,</li> <li>• Display: LCD or better for the visualization of at least: heart rate, systolic, diastolic and mean arterial pressure.</li> <li>• Measurement range Pressure: approx. between 0 to 299 mmHg</li> <li>• Measurement range Pulse: approx. between 40 to 180 beats / min</li> <li>• Inflation: Automatic controlled by electric pump</li> <li>• Deflation: Automatic pressure release valve</li> <li>• Cuff features: <ul style="list-style-type: none"> <li>o Reusable adult-use cuff, sizes: (25–36 cm) <math>\pm</math> 5 cm</li> <li>o Material: durable, non-deformable and washable (at 30°C) material like nylon.</li> <li>o Reinforced at both sides.</li> </ul> </li> </ul>	<p>50</p>

<ul style="list-style-type: none"> <li>o With double Velcro fastening, enabling a tight and secure fit around arms.</li> <li>• Tube length: at least 70 cm.</li> </ul> <p><b>Accessories:</b></p> <ul style="list-style-type: none"> <li>• Rechargeable battery charger.</li> <li>• 1 Waterproof Carry pouch,</li> <li>• 1 Adjustable Arm Cuff adult (22-36 cm)</li> </ul> <p><i>NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product, even if they are not included in these required technical specifications must be included and listed in the offer.</i></p>	
<p><b>Documentation required:</b></p> <p>Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Manufacturer brochure or data sheet including at least all technical specifications required.</li> <li>• User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal.</li> <li>• Manufacturer authorization Letter.</li> <li>• Free Sale Certificate.</li> <li>• <b>Warranty Letter:</b> The equipment must be new, not used. At least 24 months from the date of commissioning.</li> </ul> <p><b>NOTE: All the documents must be submitted in English and French language as mandatory.</b></p>	
<p><b>Regulatory approvals required:</b></p> <p>Bidder shall furnish <b>documentary evidence</b> to demonstrate that the good offered is approved according:</p> <ul style="list-style-type: none"> <li>• Valid manufacturing licenses.</li> <li>• And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> <li>o European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIa devices, or</li> <li>o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or</li> <li>o WHO-GMP certificate or similar.</li> </ul> </li> </ul>	
<p><b>Safety &amp; product Standards:</b></p> <p>Bidder shall furnish the following documents:</p> <ul style="list-style-type: none"> <li>• Valid ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.</li> <li>• Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety &amp; regulatory standards: <ul style="list-style-type: none"> <li>o IEC 80601-2-30: Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers .</li> <li>o IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> <li>o IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and test</li> </ul> </li> </ul>	