

## Section II: Schedule of Requirements

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### **Section II.1: Summary of the required goods and services**

The list of the required goods with quantities and specifications as well as associated services are detailed in Section IV: Draft Contract for goods, Annex III - Schedule of Requirements.

### **Section II.2 Details of Service Requirements**

The compliance to the below requirements on per item basis can be indicated by the supplier in the relevant Returnable Bid Schedule.

#### **Section II.2a - Manufacturer's Authorisation**

If the Bidder is not the manufacturer or producer of the Goods it offers to supply, s/he shall submit the Manufacturer's Authorization using the form included in Section III: Returnable Bidding Forms, Form F - Manufacturer's Authorisation Form - to demonstrate that it has been duly authorised by the manufacturer or producer of the Goods to submit a bid and supply the goods/products.

If the bidder is a manufacturer of one or more items, authorization(s) shall be required only for the balance of items from the respective manufacturers.

For Agents quoting in the name of a manufacturer of one or more item(s): Proper authorization from the manufacturer for Bids from Agents plus legally enforceable authorization(s) for the balance of items from the respective manufacturers must be submitted.

Authorisation must comply with the following:

- Offered on the letterhead of the manufacturer;
- Signed by an authorised representative of the manufacturer;
- Contact details of the manufacturer included;
- Clear authorisation from manufacturer to supplier for sales of designated item (brand + type), or sales of manufacturer's items in designated country confirming:
  - Manufacturer's full guarantee and warranty in accordance with Clause 5.5 of the General Conditions of Contract for the Provision of Goods and Services, with respect to the goods offered by the bidder;
  - Availability of spare parts, consumables, reagents etc and related service support in the Republic of Uzbekistan for the coming 5 years.

Manufacturer's Authorisation shall be required only for the major equipment. Supply of non-critical parts, consumables, reagents, etc. shall not require manufacturer's authorisation.

#### **Section II.2b - Manufacturer & Supplier Certification**

For the purposes of this tender a supplier can either be a distributor (intermediary who does not manufacture but only provides the health product) or the manufacturer of a product.

**Requirements for distributors:** Distributors of medical devices and health products shall:

1. Have all the licences and authorizations required under national legislation of the country of operation issued by the national regulatory authority or other relevant entity; and
2. Have a Quality Management System (preferably compliant to ISO 9001 or other applicable quality management system requirements). Relevant certificates, licences, permits, authorisations or other documents, as may be applicable, attesting to existence of such QMS shall be provided as requested.

**Requirements for Manufacturers:** Manufacturers of Medical Devices and other health products shall, subject to applicable regulations:

1. Have a duly authorised manufacturing licence, valid for all relevant manufacturing sites and activities performed, issued by the National Regulatory Authority of the country of manufacturing and be Good

Manufacturing Practice (GMP) compliant according to the applicable regulatory framework and national regulations; and

2. Have a valid and certified QMS, according to the following requirements:
  - a. latest versions in force ISO 13485 or any of the applicable ISO standard (ISO 9001 etc.), when the first is not applicable, or an equivalent QMS standard (equivalence defined below from b. to c.); and
  - b. the QMS shall include the scope and the locations and facilities where the relevant activities are performed;
  - c. The QMS shall be issued by Conformity Assessment Bodies (CABs), Notified or Accredited bodies recognised by the Regulatory Authority of one of the Global Harmonization Task Force (GHTF) Founding Member countries (Australia, Canada, EU, Japan, US).

**Manufacturer's commitment to sustainability:** It is preferred that the manufacturing facilities, where the offered equipment are manufactured, possess a valid ISO 14001 Environmental Management System (EMS) certificate. In the absence of ISO 14001, an EMS certificate issued by a competent national body can be considered.

**A valid copy of all the certificates shall be submitted.**

### **Section II.2c - Product Certification**

Compliance with internationally recognized standards of quality is expected for all the offered items:

- Compliance and certification to Regulation (EU) 2017/745 (MDR) or Directive 93/42/EEC or FDA approval or EU type Declaration of Conformity, issued by the manufacturer and verified by the Notification Body (NB). However, other certificates issued in compliance with the regulatory frameworks of the founder countries of the Global Harmonization Task Force (GHTF) are also acknowledged, if properly explained by the bidder (for all items offered/types of equipment).
- Specific Certification requirements are specified in the Technical Specifications of each particular item.