



Terms of Reference /Technical Specification Clauses

Item Name: Multiple High Frequency Tube Sealing for Blood Products Bags: Individual devices can be combined freely or used as standalone devices

I- Specifications:

- Fixed Sealers that can be combined to perform several tube sealing simultaneously.
- Hermetic sealing of the PVC tubing containing blood and blood components ensuring sterility of the blood and blood component in the blood bag.
- Sealing that is wide enough to allow for the perfect breakability of the tubing without breaking the sterility of the two sections produced.
- A homogeneous heating temperature in order to avoid the melting of the tubes during the sealing process.
- Low hemolysis (hemolysis free sealing)
- Must be compatible to sealed different types and sizes of blood bag tubes (up to 6,5 mm outer diameter and max 1 mm wall thickness) that the Lebanese Red Cross Blood Transfusions Center may use.
- **Material:** should be made of medical-grade stainless steel to ensure durability.
- **Electrical Specifications;** Input Voltage: Compatible with Lebanese electrical standards.
- Quick sealing time: 1 to 3 seconds.
- Indication lamps for power, ready and sealing.
- Tube detection: automatic
- Operating temperature : +5 to +40 °C
- Operation: Continuous
- Provided with a splash guard,
- Built-in cooling system (example: Fan....) as a safety features for overheat.
- During operation, the device must be silent and must not emit any fumes or particles.
- The device is subject to CE marking, FDA approved or ISO certifications.

II- Training:

Demonstration and continued comprehensive training for lab staff and support services until familiarity with the system.

III- Documents to be delivered:

- Product certifications.
- Warranty
- Installation Qualification (IQ) and Operational Qualification (OQ).
- Supplier Qualification documentation (to be completed using form provided by LRC Blood Transfusion Services "**QUAL-FOR-024 Supplier Qualification Questionnaire/QMS Compliance**").
- Should provide electronic and hard copies of User Manual (English), Service manual (English) and Complete construction details with respect to material specifications.

IV- Accessories required:

Any required accessories to be suggested and provided by the company.

V – Transport, installation, and setup

Assured by the company.