Neonatal Resuscitation Set

S.N.	Purchaser's Specifications	Bidder's Offer
	Resuscitation Set	
	Manufacturer	
	Brand	
	Type / Model	
	Country of Origin	
1.	**Description of Function**	
1.1	A complete manual ventilation assembly designed to facilitate resuscitation of newborns in emergencies and clinical environments.	
2.	**Operational Requirements**	
2.1	The set must be portable, hand-operated, and fully reusable. All components must be designed for easy disassembly and cleaning.	
3.	**System Configuration**	
3.1	Complete Resuscitation Set including: Self-inflating bag, patient safety (pop off) valve, oxygen reservoir, face masks (3 sizes), and carrying case.	
4.	**Technical Specifications**	
4.1	**Self-inflating Resuscitator Bag:** Capacity between **250 ml and 350 ml**. Made from high-grade, translucent **medical silicone rubber** for high-recoil and visual inspection of internal cleanliness.	
4.2	**Pressure Limiting Valve:** Integrated safety valve pre-set at **40-45cmH_2O** to prevent barotrauma. Must include a manual lock/override mechanism for emergency high-pressure ventilation.	
4.3	**Dead Space:** The patient valve must have minimal internal dead space <7ml to prevent CO_2 re-breathing in small neonates.	
4.4	**Intake Valve:** Must include an integrated oxygen reservoir socket for the attachment of an oxygen reservoir bag.	
4.5	**Decontamination:** All silicone parts and valves must be autoclavable at 134 °C for at least 50 cycles without degradation.	
4.3	Mask-The mask or facemask is connected to the bag and covers the mouth and nose of the newborn who is being resuscitated -Size 0 for preterm and low-weight baby, round type, diameter 35–50 mm - Size 1 for term baby, round type, diameter 50–65 mm translucent - Size 2. **Oxygen Reservoir:** One (1) Silicone or PVC reservoir bag, minimum 600ml capacity **Oxygen Tubing:** One (1) set of star-lumen, kink-resistant tubing, minimum 2 meters in length	
5.	**Accessories, spares and consumables**	

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5.1	**Accessories:** - Resuscitator bag and masks supplied as a complete set, along with the non-rebreathing patient valve	
6.	**Operating Environment**	
6.1	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Climate, Temperature, Humidity, etc.	
7.	**Standards and Safety Requirements**	
7.1	Must submit ISO 13485:2016 **AND**	
7.2	CE or USFDA approved product certificate.	
8.	**User Training**	
8.1	Must provide user training (including how to use and maintain the equipment).	
9.	**Warranty**	
9.1	Comprehensive warranty for 2 years after acceptance.	
10.	**Maintenance Service During Warranty Period**	
10.1	Standard warranty conditions are applicable.	
11.	**Installation and Commissioning**	
11.1	Must supply a preassembled unit, ready to use.	
12.	**Documentation**	
12.1	User's manual shall be supplied in English.	