

CODE NO:

Device Name : *(Apheresis Units)* blood donor

DATE: 2025

- ❖ **Application:** automate the separation performed on blood from healthy donors include plasmapheresis, plateletapheresis (also called thrombocytophoresis), And Erythrocytophoresis (PRBCS) and leukopheresis.
- ❖ **FDA CLEARANCE CE MARK :** Yes
- ❖ **Type :** Automated
- ❖ **Separation method:** centrifugation.
- ❖ **Centrifuge, rpm:** ≥ 1500 .
- ❖ **Flow type:** continuous or Intermittent.
- ❖ **venous access :** single or double
- ❖ **Inlet rate, ml/min:** range $\geq (0 -90)$.
- ❖ **Anticoagulant ratio (ratio of the volume of anticoagulant to the volume of blood):** can be set automatic or manual.
- ❖ **Warmer:** according to manufacturers.
- ❖ **Extracorporeal priming volume, ml:** minimal volume preferred.
- ❖ **Programs:** The types of programmable procedures should be specified.
- ❖ **monitors/alarms :** yes , to be specified
- ❖ **data management:** yes
- ❖ **Power requirements:** 220-240v, 50-60 Hz, three pin G type plug.
- ❖ **Battery backup or UPS (include voltage stabilizer) to complete the cycle.**
- ❖ **Environmental requirements:** the equipment suitable for working in the climate conditions of Iraq in terms of temperature & humidity