BLOOD COLLECTION TUBES TECHNICAL SPECIFICATIONS

Product Name:	VACUSERA® Blood Collection Tubes

1. Intented Use:

VACUSERA® Blood Collection Tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory.

2. Physical Properties:

a) Raw Materials

Tubes are made from PET (poly ethylene terapthalate) material. They should be colourless and transparent.
Tube caps are made from PE (polyethylene) material. Their colours may differ according to the additive that the tube contains.
Rubber stoppers are made from rubber material and are latex free.

b) Dimentions

There are three different type of tubes according to their dimentions:

- 13x75 mm
- 13x100 mm
- 16x100 mm

and two different type of caps & rubbers with 13 mm and 16 mm dia that could fit in these tubes. All detailed dimentions are in the technical drawings.

3. Chemical Properties:

a) Additives

VACUSERA® Blood Collection Tubes comes with 16 different additives and their combinations. They may be:

- EDTA Dipotassium Salt
- EDTA Tripotassium Salt
- EDTA Tripotassium Salt-Aprotinin
- CTAD Citrate theophylline adenosine dipyridamole
- Trisodium Citrate 9:1
- Trisodium Citrate 4:1
- Sodium Fluoride / EDTA
- Sodium Fluoride/Potassium Oxalate
- Sodium Fluoride + Na2EDTA
- Lithium Heparin
- Sodium Heparin
- None / Clot Activator
- Buffered Citrate 0.109 M
- ACD-A Solution A
- ACD-B Solution B
- Thrombin Based Tube

4. Biological Properties

Since VACUSERA® Blood Collection Tubes are in vitro diagnostic medical devices, they have no human contact and therefore they don't have to be biocompatible.

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5. Applicable Standards

ISO 6710 " Single-use containers for venous blood specimen collection"
EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2 Packaging for terminally sterilized medical devices - Part 2:Validation requirements for forming, sealing and assembly processes
EN ISO 20417 Information supplied by the manufacturer with medical devices
EN ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971 Medical devices - Application of risk management to medical devices
ISO 11137-1 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2 Sterilization of health care products- Radiation - Part 2: Establishing the sterilization dose
ISO 11137-3 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects

6. Sterilization

VACUSERA® Blood Collection Tubes are placed in the market as sterile. Products are sterilized using radiation sterilization. Sterilization process shall be validated.

7. Packaging

VACUSERA® Blood Collection Tubes are packaged by using styrofoam and stretch film. Each package contains 100 tubes (which is called a rack) and each box contains 1200 tubes (12 rack).

Prepared by **Quality Assurance Specialist**	**Approved by** **Factory Manager** DİSERA TIBBİ MALZEME LOJİSTİK SANAYİ ve TİC. A.Ş. Gaziemir V.D. 301 053 3601 **Umut ERSOY**