BLOOD COLLECTION TUBES TECHNICAL DATA SHEET

VACUSERA® SERUM CLOT ACTIVATOR

Blood Collection Tubes

Ref No	GMDN Code	Draw Vol (ml)	Label Type	Additive	Tube Size (mm)	Color	Cap Color
234201	42386	1	Paper	CLOT ACTIVATOR	13X75	Red	
234202	42386	2	Paper	CLOT ACTIVATOR			
234203	42386	3	Paper	CLOT ACTIVATOR			
234204	42386	4	Paper	CLOT ACTIVATOR			
235206	42386	6	Paper	CLOT ACTIVATOR	13X100		
236209	42386	9	Paper	CLOT ACTIVATOR	16X100		
236200	42386	10	Paper	CLOT ACTIVATOR			
434201	42386	1	Transparent	CLOT ACTIVATOR	13X75		
434202	42386	2	Transparent	CLOT ACTIVATOR			
434203	42386	3	Transparent	CLOT ACTIVATOR			
434204	42386	4	Transparent	CLOT ACTIVATOR			
435206	42386	6	Transparent	CLOT ACTIVATOR	13X100		
436209	42386	9	Transparent	CLOT ACTIVATOR	16X100		
436200	42386	10	Transparent	CLOT ACTIVATOR			

DİSERA TIBBİ MALZEME LOJİSTİK SANAYİ VE TİCARET A.Ş.
GAZİEMİR VD. : 301 053 3601 Tic.Sic.No : Merkez 123171 K - 10769 Mersis No : 0301053360100013
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Ref No	GMDN Code	Draw Vol (ml)	Label Type	Additive	Tube Size (mm)	Color	Cap Color
234202DLR	42386	2	Paper	CLOT ACTIVATOR	13X75	Light Red	
234204DR	42386	4	Paper	CLOT ACTIVATOR		Red	
235206DR	42386	6	Paper	CLOT ACTIVATOR	13X100		
236200DR	42386	10	Paper	CLOT ACTIVATOR	16X100		

1. Intended Use:

VACUSERA® Serum Clot Activator Tubes are used to collect the blood required for tests performed in biochemistry laboratories. These tubes are designed for fast, clear and easy separation of serum. They are used to coagulate blood and to obtain serum by centrifugation. Used for biochemistry, and hormone tests.

2. Information About The Manufacturer

Manufacturer: Disera Tıbbi Malzeme Lojistik Sanayi ve Ticaret A.Ş
Country of Origin: Turkey
EN ISO 13485:2016 Cert. n 31723701 Released by Szutest

3. Applicable Standards

No	EXPLANATION OF STANDARD
1	EN ISO 13485:2016 Medical devices — Quality Management Systems — Requirements for Regulatory Purposes
2	EN ISO 15223-1:2021 Medical Devices — Symbols to be Used with Information to be Supplied by The Manufacturer — Part 1: General Requirements

3	EN ISO 20417:2021 Medical Devices - Information to be Supplied by the Manufacturer
4	EN ISO 14971:2019 Medical Devices — Application of Risk Management to Medical Devices
5	EN 62366-1:2015 Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
6	EN ISO 11137-1:2015 Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
7	EN ISO 11137-2:2015 Sterilization of Health Care Products — Radiation — Part 2: Establishing the Sterilization Dose
8	EN ISO 11137-3:2017 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control
9	EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
10	EN ISO 11737-2:2020 Sterilization of Health Care Products — Microbiological Methods — Part 2: Tests of Sterility Performed in The Definition, Validation and Maintenance of a Sterilization Process
11	ASTM F 1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
12	EN ISO 6710 :2017 Single-Use Containers for Human Venous Blood Specimen Collection
13	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilised medical devices
14	EN ISO 14644-1:2015 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
15	EN ISO 14644-2:2015

	Cleanrooms And Associated Controlled Environments — Part 2: Monitoring to Provide Evidence of Cleanroom Performance Related to Air Cleanliness by Particle Concentration
16	EN ISO 14644-3:2019 Cleanrooms And Associated Controlled Environments — Part 3: Test Methods
17	98/79/EC Directive of In vitro diagnostic medical devices
18	EN 13612: 2002 Performance evaluation of in vitro diagnostic medical devices
19	EN ISO 18113 -1 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)

4. Product Specifications

Tube material:	Polyethylene teraphthalate (PET)
Cap material (outer shield):	Polyethylene (low density polyethylene resin)
Rubber material (inner cap):	Bromobutyl elastomers
Additives:	Clot Activator (Silica Particles)
Additive Filling Form:	Spray
Gel Specification	Acrylic gel
Fill indicator:	Yes
Expiry (months):	18 months
Storage conditions:	Do not expose to direct sunlight. Store between +4 and 35 ° C.

5. Physical Properties

a) Raw Materials:

Tubes are made from PET (polyethylene terephthalate) material. They should be colorless and transparent.

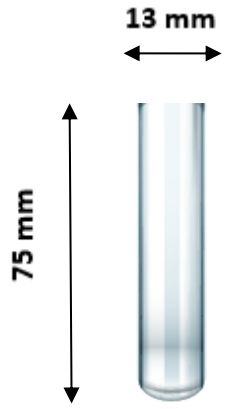
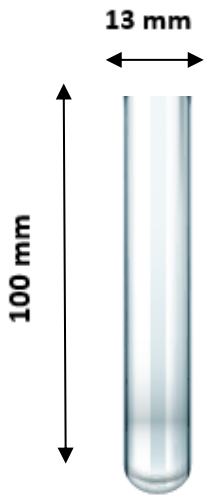
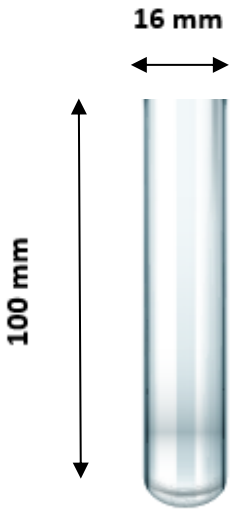
Tube caps are made from PE (polyethylene) material. Their colors may differ according to the additive that the tube contains.

Rubber stoppers are made from butyl elastomers.

All components are latex-free.

b) Dimensions

There are three different types of PET tubes according to their dimensions

13 x 75 mm PET Tube	13 x 100 mm PET Tube	16 x 100 mm PET Tube
		

There are PE caps with two different diameters (13mm & 16mm) that could fit into these PET tubes.

Accordingly, there are stoppers with 13 mm and 16 mm diameter that could fit in these PE caps and PET tubes.

All detailed dimensions are represented in the technical drawings.

6. Packaging

100 pieces of VACUSERA® Blood Collection Tubes are lined up in a styrofoam and wrapped with a shrink film. Each of these packages is called as rack. 12 racks are placed in a carton box and each box contains 1200 tubes.

Outer box dimensions for 13x75mm tubes: 36.0 X 53.5 X 18.5 mm
Outer box dimensions for 13x100mm tubes: 36.0 X 53.5 X 24.0 mm
Outer box dimensions for 16x100mm tubes: 38.0 X 56.5 X 24.0 mm

7. Sterilization

VACUSERA® Blood Collection Tubes are placed in the market as sterile. Products are sterilized using radiation sterilization. Sterilization process shall be validated.
Internamente sterility: SAL 10^{-6} (SAL= sterility assurance level) Standards: EN ISO 11137-2:2015; EN 556:2001/AC:2006

8. Label Information

	Tube Label	Rack Label	Carton Label
Company name and address of the manufacturer	+	+	+
Ref No (Product Code)	+	+	+
Lot No	+	+	+
Sterile (symbol) and method of sterilization	+	+	+
CE mark and single use symbol	+	+	+
Fill volume	+	+	+
Expiration Date	+	+	+
Product name and short description	+	+	+
Instructions for use (pictograms)	-	+	+
Quantity per package	-	+	+

Storage instructions	-	+	+
Primary barcode	-	+	+
Secondary barcode	-	+	+
Sterility indicator	-	-	+

Symbols on the label	Description of the Symbols	Tube Label	Rack Label	Box Label
	Reference Number	✓	✓	✓
	Batch Code	✓	✓	✓
	Use by	✓	✓	✓
	Single Use	✓	✓	✓
	Keep away from sunlight		✓	✓
	Radiation Sterilization	✓	✓	✓
	See the Instruction for Use		✓	✓
	In Vitro Diagnostic Device	✓	✓	✓
	Temperature Limits		✓	✓
	CE symbol	✓	✓	✓

9. Instructions For Use

For more detailed information and usage instructions, please check the IFU document.