


## BLOOD COLLECTION TUBES TECHNICAL DATA SHEET

### VACUSERA® SERUM GEL AND CLOT ACTIVATOR Blood Collection Tubes



Ref No	GMDN Code	Draw Vol (ml)	Label Type	Additive	Tube Size (mm)	Color	Cap Color
234302	41128	2	Paper	Clot Activator and Gel	13x75	GOLD	
234304	41128	2.5	Paper	Clot Activator and Gel			
234303	41128	3.5	Paper	Clot Activator and Gel			
235304	41128	4	Paper	Clot Activator and Gel	13x100		
235305	41128	5	Paper	Clot Activator and Gel			
236308	41128	8	Paper	Clot Activator and Gel	16x100		
236309	41128	9	Paper	Clot Activator and Gel			
434302	41128	2	Transparent	Clot Activator and Gel	13x75		
434304	41128	2.5	Transparent	Clot Activator and Gel			
434303	41128	3.5	Transparent	Clot Activator and Gel			
435304	41128	4	Transparent	Clot Activator and Gel	13x100		
435305	41128	5	Transparent	Clot Activator and Gel			

**DİSERA TIBBİ MALZEME LOJİSTİK SANAYİ VE TİCARET A.Ş.**


GAZİEMİR VD. : 301 053 3601 Tic.Sic.No : Merkez 123171 K - 10769 Mersis No : 0301053360100013





Merkez : Karabağlar Mah. 5758 Sk. No:4 H/11 - Karabağlar / İZMİR

Tel : +90 (0232) 264 66 68 [info@disera.com.tr](mailto:info@disera.com.tr)

Fabrika : İbni Melek Mah. Tosbi Yol 5 Sk. No: 46 Tire / İZMİR

Faks : +90 (0232) 264 84 00 [www.disera.com.tr](http://www.disera.com.tr)

436308	41128	8	Transparent	Clot Activator and Gel	16x100		
236309	41128	9	Transparent	Clot Activator and Gel			
235315	57899	5	Paper	Clot Activator Thrombin and Gel	13x100	ORANGE	

Ref No	GMDN Code	Draw Vol (ml)	Label Type	Additive	Tube Size (mm)	Color	Cap Color
234304DLG	41128	2.5	Paper	Clot Activator and Gel	13x75	LIGHT GOLD	
234303DG	41128	3.5	Paper	Clot Activator and Gel		LIGHT GOLD	
235305DG	41128	5	Paper	Clot Activator and Gel	13x100	GOLD	
236309DG	41128	9	Paper	Clot Activator and Gel	16x100	GOLD	

## 1. Intended Use:

VACUSERA® Serum Gel and Clot Activator Tubes are used in tests, which are applied in clinic biochemistry and immunology laboratory. Thanks to special activator, which is plastered inside wall of the tubes, blood coagulation occurs. Additionally, inert gel that stays bottom of the tube, moves upward position of the tube and creates a barrier between serum and blood cells during centrifugation. This provides to gain high quality serum.

In addition, VACUSERA® Thrombin Based Serum Gel Tubes are used in tests applied in clinical biochemistry and immunology laboratories. VACUSERA® Thrombin Tubes allow rapid blood clotting (maximum 5 minutes) thanks to its special activator coated on the inner walls of the tube, which meets the needs of patients with blood clotting problems or units that require rapid test results. The inert gel contained in the tubes forms a barrier between serum and clot after centrifugation allowing to get high-quality serum specimen.

## 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

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### 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

<b>Tube material:</b>	Polyethylene terephthalate (PET)
<b>Cap material (outer shield):</b>	Polyethylene (low density polyethylene resin)
<b>Rubber material (inner cap):</b>	Bromobutyl elastomers
<b>Additives:</b>	Clot Activator (Silica Particles, Thrombin for 235315), Gel
<b>Additive Filling Form:</b>	Spray
<b>Gel Specification</b>	Acrylic gel
<b>Fill indicator:</b>	Yes
<b>Expiry (months):</b>	18 months
<b>Storage conditions:</b>	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.

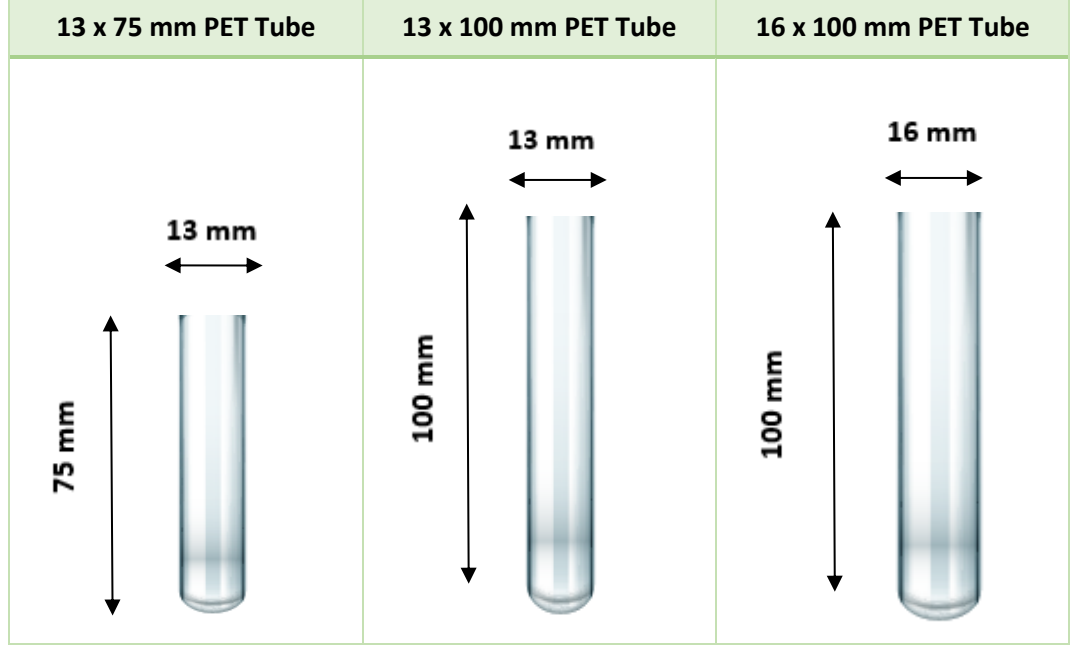
Tube caps are made from PE (polyethylene) material. Their colors may differ according to the additive that the tube contains.

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



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<sup>-6</sup> (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.