

## EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

### Full Quality Assurance System

Certificate Number: 2195-MED-1729001

**Manufacturer:**

**DİSERA TIBBİ MALZEME LOJİSTİK SANAYİ VE TİCARET ANONİM ŞİRKETİ**  
Head Office: 5758 Sok. No:4H/11 Karabağlar/İzmir/TÜRKİYE  
Factory: İbni Melek OSB Mah. Tosbi Yol 5 Sokak No:46  
Tire/İzmir/TÜRKİYE

**Product(s):**

- (1) Sterile Pressure Activated Safety Blood Lancet
- (2) Sterile Vaginal Speculum
- (3) Sterile Luer Adapter
- (4) Sterile Blood Collection Needle
- (5) Sterile Blood Collection Set
- (6) Sterile PRP Tube Set

**Model(s):**

Product specifications are stated on the following page(s).

**Reference Report No:**

MM0645-P006-R01, MM0645-P006-R02, MM0645-P006-R03, MM0645-P006-R04,  
MM0645-P007-R01, MM0645-P008-R01, MM0645-P010-R01

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

**This EC certificate is valid till 2024-05-26.**

Issue Date: 2017-10-17  
Revision No.: 05 Rev.  
Revision Date: 2021-04-22



Rukiye BALKAN  
Deputy General Manager



**Certificate Number: 2195-MED-1729001**

**Product Specifications:**

**(1) Sterile Pressure Activated Safety Blood Lancet**

- Sterile Vacusera Pressure Activated Safety Blood Lancet 18G 1,8 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 18G Blade 1,8mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 21G 1,8 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 21G 2,2 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 21G 2,8 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 21G Blade 1,8mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 23G 1,8 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 23G 2,2 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 25G 1,8 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 26G 1,8 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 28G 1,5 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 28G 1,8 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 30G 1,5 mm
- Sterile Vacusera Pressure Activated Safety Blood Lancet 30G 1,8 mm

**(2) Sterile Vaginal Speculum**

- Sterile ALTECH Vaginal Speculum Small
- Sterile ALTECH Vaginal Speculum Medium
- Sterile ALTECH Vaginal Speculum Large

**(3) Sterile Luer Adapter**

- Sterile Vacusera Luer Adapter 20G
- Sterile Vacusera Luer Adapter 20G + Standard Holder

**(4) Sterile Blood Collection Needle**

- Sterile Vacusera Blood Collection Needle 18Gx1½" (1,2x38mm)
- Sterile Vacusera Blood Collection Needle 20Gx1½" (0,9x38mm)
- Sterile Vacusera Blood Collection Needle 21Gx1½" (0,8x38mm)
- Sterile Vacusera Blood Collection Needle 22Gx1½" (0,7x38mm)
- Sterile Vacusera Blood Collection Needle 23Gx1½" (0,6x38mm)
- Sterile Vacusera Blood Collection Needle 20Gx1½" (0,9x38mm) - Vision
- Sterile Vacusera Blood Collection Needle 21Gx1½" (0,8x38mm) - Vision
- Sterile Vacusera Blood Collection Needle 22Gx1½" (0,7x38mm) - Vision
- Sterile Vacusera Blood Collection Needle 23Gx1½" (0,6x38mm) - Vision



Certificate Number: 2195-MED-1729001

## Product Specifications:

### (4) Sterile Blood Collection Needle

- Sterile Vacusera Blood Collection Needle – Vision + Safety Holder 21Gx1½" (0,8x38mm)
- Sterile Vacusera Blood Collection Needle – Vision + Safety Holder 22Gx1½" (0,7x38mm)
- Sterile Vacusera Blood Collection Needle + Safety Holder 18Gx1½" (1,2x38mm)
- Sterile Vacusera Blood Collection Needle + Safety Holder 20Gx1½" (0,9x38mm)
- Sterile Vacusera Blood Collection Needle + Safety Holder 21Gx1½" (0,8x38mm)
- Sterile Vacusera Blood Collection Needle + Safety Holder 22Gx1½" (0,7x38mm)
- Sterile Vacusera Blood Collection Needle + Safety Holder 23Gx1½" (0,6x38mm)
- Sterile Vacusera Blood Collection Needle 18Gx1" (1,2x25mm)
- Sterile Vacusera Blood Collection Needle 20Gx1" (0,9x25mm)
- Sterile Vacusera Blood Collection Needle 21Gx1" (0,8x25mm)
- Sterile Vacusera Blood Collection Needle 22Gx1" (0,7x25mm)
- Sterile Vacusera Blood Collection Needle 23Gx1" (0,6x25mm)
- Sterile Vacusera Integrated Safety Needle 21Gx1¼" (0,8x32mm)
- Sterile Vacusera Integrated Safety Needle 22Gx1¼" (0,7x32mm)
- Sterile Vacusera Blood Collection Holder with Male Luer Lock
- Sterile Vacusera Blood Collection Holder with Female Luer Lock

### (5) Sterile Blood Collection Set

- Sterile Vacusera Blood Collection Set with Safety Shield 21Gx3/4"x7"
- Sterile Vacusera Blood Collection Set with Safety Shield 21Gx3/4"x12"
- Sterile Vacusera Blood Collection Set with Safety Shield 22Gx3/4"x7"
- Sterile Vacusera Blood Collection Set with Safety Shield 22Gx3/4"x12"
- Sterile Vacusera Blood Collection Set with Safety Shield 23Gx3/4"x7"
- Sterile Vacusera Blood Collection Set with Safety Shield 23Gx3/4"x12"
- Sterile Vacusera Blood Collection Set with Safety Shield 25Gx3/4"x7"
- Sterile Vacusera Blood Collection Set with Safety Shield 25Gx3/4"x12"
- Sterile Vacusera Blood Collection Set with Safety Shield + Holder 21Gx3/4"x7"
- Sterile Vacusera Blood Collection Set with Safety Shield + Holder 21Gx3/4"x12"
- Sterile Vacusera Blood Collection Set with Safety Shield + Holder 22Gx3/4"x7"
- Sterile Vacusera Blood Collection Set with Safety Shield + Holder 22Gx3/4"x12"
- Sterile Vacusera Blood Collection Set with Safety Shield + Holder 23Gx3/4"x7"
- Sterile Vacusera Blood Collection Set with Safety Shield + Holder 23Gx3/4"x12"
- Sterile Vacusera Blood Collection Set with Safety Shield + Holder 25Gx3/4"x7"
- Sterile Vacusera Blood Collection Set with Safety Shield + Holder 25Gx3/4"x12"

### (6) Sterile PRP Tube Set

- Sterile Vacusera PRP Tube Set with Gel
- Sterile Vacusera PRP Tube Set
- Sterile Vacusera PRF Tube

