

	<b>TEKNİK DOSYA – TECHNICAL FILE</b> <b>ÜRÜN &amp; ÜRETİM BİLGİLERİ</b> <b>PRODUCT &amp; MANUFACTURING INFORMATION</b>				<b>TF – 02</b>
Yayın Tarihi	01.08.2021	Revizyon No	00	Revizyon Tarihi	---

## STERİL VAJİNAL SPEKULUM (Sterile Vaginal Speculum)

### Ürün Tanımı (Product Information)

Vaginal Speculum is a biocompatible, sterile, disposable product. It consists of the parts defined below;

\* Speculum: Made of medical grade PVC. It is transparent, unbreakable and lightweight.

\* Lock: High density polyethylene in different colors. Lock colors are as follows;

Small-Red

Medium-Blue,

Large-Green

It has an easy-to-use design. It is easily holdable.

It has a transparent structure that provides high vision quality.

It has a support frame aperture providing wide viewing angle.

There is a secure lock system that allows fixing at the desired angle. The locking system used enables one-handed and fast operation. The tongue used in the locking system is semi-fixed in a slot on the trigger part of the speculum and has a feature on the handle where the specialist can fix the speculum at any angle. The lock system can be activated easily with one hand. The tip and all parts are ergonomically designed with rounded edges that prevent tissue damage. There are no sharp and angular surfaces that can damage the tissue.

Made of non-breakable material

### Kullanım Amacı (Intended Use)

It ensures that the vagina is opened in the desired amount and remains open during the working period of the physician. In this way, the physician can comfortably control the patient and work comfortably.

**Sınıflandırma MDR (AB) 2017/745/ EK IX**  
**Classification MDR 2017/745 EU Annex IX**

Sınıf I, Kural 1  
Class I, Rule 1

**GMDN Kodu & Adı**  
**GMDN Code & Name**

**37468**  
Speculum, vaginal, single use

**Ambalaj**  
**Packing**

Parça Adı	Adet
Vajinal Spekulum	1

**Biyolojik Değerlendirme**  
**Biological Evaluation**

The biological evaluation of the product was carried out according to the EN ISO 10993-1 standard. Biological Evaluation Table-2 is as in the Biological Evaluation Table in EN ISO 10993-1 standard. Based on this table, biocompatibility tests were made for the main raw material of the product, test reports are in ANNEX-5.

Tipleri Types	Model No, Ref No Model No	Ürün Product	Steril mi? Sterile?		Sterilizasyon Metodu Sterilization Method	Raf Ömrü Shelf Life
			Evet Yes	Hayır No		
Small	T201791		X	---	R	5 yıl 5 Years
Medium	T201792					
Large	T201793					