

## EC DECLARATION OF CONFORMITY

*According to the Annex II 93/42/EEC Directive*

**Manufacturer Address** :Disera Tıbbi Malzeme Lojistik Sanayi ve Ticaret A.Ş  
: İbni Melek OSB mah. Tosbi Yol. 5 Sokak No:46  
Tire, İzmir/Türkiye

**Product Classification:** :VACUSERA® PRP Tube Set  
: 93/42/EEC Directive Class II b Rule 3

**GMDN Kod** : 46923

We herewith declare under our sole responsibility that the above mentioned products the following 93/42/EEC Medical Device Directive and applicable Standarts. All supporting documentations are premises of the manufacturer.

**Conformity Assesment Procedure:** 93/42/EEC Directive , Annex II (Except Article 4)

**Notified Body:** SZUTEST Uygunluk Deęerlendirme A.Ş.  
Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul  
**Notified Body Number:** 2195

**Certificate No:** 2195-MED-1729001, valid until 26.05.2024

**CE Marking Beginning Date:** 16.09.2019

### STANDARDS

Refer to List of applicable (harmonized) standards in tecnical documentation.

**Place, Date** : İzmir, 04.06.2020

**Signature** : Kenan Deniz BÜYÜKAKMAN  
General Manager

**DİSERA**  
TIBBİ MALZEME LOJİSTİK SAN. ve TİC. A.Ş.  
Mirk.: Karabaęlar Mh. 5758 Sokak No: 4 H/11 Karabaęlar  
Tel: (0.232) 264 66 00 Fax: (0.232) 264 84 00 İZMİR  
Fabrika: İbni Melek OSB. Mah. Tosbi Yol 5 Sokak No. 46  
Tel: (0232) 513 51 21 Fax: 513 51 20 Tire/İZMİR  
Göztepe V.D. 301 053 3601

**ANNEX TO THE  
DECLARATION of CONFORMITY**

**Product** :VACUSERA® PRP Tube Set

**Classification:** : 93/42/EEC Directive Class II b Rule 3

**Conformity Assesment Procedure** : 93/42/EEC Directive , Annex II (Except Article 4)

**GMDN Kod** : 46923

Product Description	Additives	GMDN Codes	GMDN Description
PRP Tube Set	Sodyum Sitrat 3.2 %	46923	The hematological concentrate system kit, platelet concentrate
PRP Tube With Gel	Sodyum Sitrat 3.2 %,Gel	46923	The hematological concentrate system kit, platelet concentrate

**Place, Date** : İzmir, 04.06.2020

**Signature** : Kenan Deniz BÜYÜKAKMAN  
General Manager

**DİSERA**  
TIBBİ MALZEME LOJİSTİK SAN. ve TİC. A.Ş.  
Mh: Karabağlar Mh. 5758 Sokak No: 4 H/11 Karabağlar  
Tel: (0 232) 264 86 77 Fax: (0 232) 264 84 00 İZMİR  
Fabrika: İbni Mülkî OSB. Mah. Tosun Yol 5 Sokak No. 46  
Tel: (0232) 513 51 21 Fax: 513 51 20 Tire/İZMİR  
Gazimir V.D. 301 053 3601