CE 2195

EC DECLARATION OF CONFORMITY

According to the Annex II 93/42/EEC Directive

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

Product **:**VACUSERA® PRP Tube Set
Classification: : *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 Değerlendirme 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
Merk.: Karabağlar Mh. 5758 Sokak No: 4 H/11 Karabağlar
Tel: (0.232) 264 66 [illegible] Fax: (0.232) 264 84 00 İZMİR
Fabrika: İbni Melek OSB. Mah. Tosbi Yol 5 Sokak No. 4
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Gaziemir V.D. 301 053 3601

CE 2195

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
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