

EC DECLARATION OF CONFORMITY

According to the annex III the 98/79/EC Directive

Manufacturer Address : Disera Tibbi Malzeme Lojistik Sanayi ve Ticaret A.Ş
: İbni Melek O.S.B mah. Tosbi Yol. 5.sokak No:46
Tire-İzmir/Türkiye

Product Classification : VACUSERA® Blood Collection Tube
: According to annex Directive 98/79/EC
Class: IVD Other Device (all device except Annex II and self testing devices)

GMDN Code : See the Annex

We herewith declare under our sole responsibility that the above mentioned products the following 98/79/EC In Vitro Diagnostic Medical Device Directive and applicable standarts. All supporting documentations are premises of the manufacturer

Conformity Assesment Procedure: 98/79/EC Directive Annex III

STANDARDS

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

Place, Date: İzmir, 27.09.2016

Signature: Kenan Deniz BÜYÜKAKMAN
General Manager



**ANNEX TO THE
DECLARATION of CONFORMITY**

Product : VACUSERA® Blood Collection Tube
Classification : According to annex Directive 98/79/EC
Class: IVD Other Device (all device except Annex II and self testing devices)
GMDN Code : See the Annex

Covers the following products in dimensions of 13x75mm, 13x100mm, 16x100mm, 8x120 mm and 9x120 mm.

Product Code	Product Description	GMDN Code	GMDN Description
234102	VACUSERA® 2 ml Z No Additive	47590	Evacuated blood collection tube, IVD, no additive
234104	VACUSERA® 4 ml Z No Additive	47590	Evacuated blood collection tube, IVD, no additive
235106	VACUSERA® 6 ml Z No Additive	47590	Evacuated blood collection tube, IVD, no additive
236109	VACUSERA® 9 ml Z No Additive	47590	Evacuated blood collection tube, IVD, no additive
434102	VACUSERA® 2 ml Z No Additive	47590	Evacuated blood collection tube, IVD, no additive
434104	VACUSERA® 4 ml Z No Additive	47590	Evacuated blood collection tube, IVD, no additive
435106	VACUSERA® 6 ml Z No Additive	47590	Evacuated blood collection tube, IVD, no additive
436109	VACUSERA® 9 ml Z No Additive	47590	Evacuated blood collection tube, IVD, no additive
234201	VACUSERA® 1 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
234202	VACUSERA® 2 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
234203	VACUSERA® 3 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator

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General Manager



Product Code	Product Description	GMDN Code	GMDN Description
234204	VACUSERA® 4 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
235206	VACUSERA® 6 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
236209	VACUSERA® 9 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
236200	VACUSERA® 10 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
434201	VACUSERA® 1 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
434202	VACUSERA® 2 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
434203	VACUSERA® 3 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
434204	VACUSERA® 4 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
435206	VACUSERA® 6 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
436209	VACUSERA® 9 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
436200	VACUSERA® 10 ml Z Serum Clot Activator	42386	Evacuated blood collection tube IVD, clot activator
234302	VACUSERA® 2 ml Z Serum Gel & Clot Activator	41128	Evacuated blood collection tube, IVD, gel, clot activator
234303	VACUSERA® 3,5 ml Z Serum Gel & Clot Activator	41128	Evacuated blood collection tube, IVD, gel, clot activator
235305	VACUSERA® 5 ml Z Serum Gel & Clot Activator	41128	Evacuated blood collection tube, IVD, gel, clot activator
236308	VACUSERA® 8 ml Z Serum Gel & Clot Activator	41128	Evacuated blood collection tube, IVD, gel, clot activator
434302	VACUSERA® 2 ml Z Serum Gel & Clot Activator	41128	Evacuated blood collection tube, IVD, gel, clot activator
434303	VACUSERA® 3,5 ml Z Serum Gel & Clot Activator	41128	Evacuated blood collection tube, IVD, gel, clot activator
435305	VACUSERA® 5 ml Z Serum Gel & Clot Activator	41128	Evacuated blood collection tube, IVD, gel, clot activator
436308	VACUSERA® 8 ml Z / Serum Gel & Clot Activator	41128	Evacuated blood collection tube, IVD, gel, clot activator

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Product Code	Product Description	GMDN Code	GMDN Description
234402	VACUSERA® 2 ml LH / Lithium Heparin	47589	Evacuated blood collection tube, IVD, lithium heparin
234404	VACUSERA® 4 ml LH / Lithium Heparin	47589	Evacuated blood collection tube, IVD, lithium heparin
235406	VACUSERA® 6 ml LH / Lithium Heparin	47589	Evacuated blood collection tube, IVD, lithium heparin
236409	VACUSERA® 9 ml LH / Lithium Heparin	47589	Evacuated blood collection tube, IVD, lithium heparin
434402	VACUSERA® 2 ml LH / Lithium Heparin	47589	Evacuated blood collection tube, IVD, lithium heparin
434404	VACUSERA® 4 ml LH / Lithium Heparin	47589	Evacuated blood collection tube, IVD, lithium heparin
435406	VACUSERA® 6 ml LH / Lithium Heparin	47589	Evacuated blood collection tube, IVD, lithium heparin
436409	VACUSERA® 9 ml LH / Lithium Heparin	47589	Evacuated blood collection tube, IVD, lithium heparin
234424	VACUSERA® 4 ml NH / Sodium Heparin	47592	Evacuated blood collection tube, IVD, sodium heparin
235426	VACUSERA® 6 ml NH / Sodium Heparin	47592	Evacuated blood collection tube, IVD, sodium heparin
236429	VACUSERA® 9 ml NH / Sodium Heparin	47592	Evacuated blood collection tube, IVD, sodium heparin
434424	VACUSERA® 4 ml NH / Sodium Heparin	47592	Evacuated blood collection tube, IVD, sodium heparin
435426	VACUSERA® 6 ml NH / Sodium Heparin	47592	Evacuated blood collection tube, IVD, sodium heparin
436429	VACUSERA® 9 ml NH / Sodium Heparin	47592	Evacuated blood collection tube, IVD, sodium heparin
234413	VACUSERA® 3 ml LH / Lithium Heparin & Gel	46054	Evacuated blood collection tube, IVD, lithium heparin,gel
235415	VACUSERA® 5 ml LH / Lithium Heparin & Gel	46054	Evacuated blood collection tube, IVD, lithium heparin,gel
236418	VACUSERA® 8 ml LH / Lithium Heparin & Gel	46054	Evacuated blood collection tube, IVD, lithium heparin,gel
434413	VACUSERA® 3 ml LH / Lithium Heparin & Gel	46054	Evacuated blood collection tube, IVD, lithium heparin,gel
435415	VACUSERA® 5 ml LH / Lithium Heparin & Gel	46054	Evacuated blood collection tube, IVD, lithium heparin,gel
436418	VACUSERA® 8 ml LH / Lithium Heparin & Gel	46054	Evacuated blood collection tube, IVD, lithium heparin,gel

Place, Date: İzmir, 27.09.2016

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DEC_Blood Collection Tube,03,27.09.16

Product Code	Product Description	GMDN Code	GMDN Description
234501	VACUSERA® 1 ml Coagulation 9NC %3,2 Sodium Citrate - Double Tube	42585	Evacuated blood collection tube IVD, sodium citrate
234502	VACUSERA® 1,8 ml Coagulation 9NC %3,2 Sodium Citrate - Double Tube	42585	Evacuated blood collection tube IVD, sodium citrate
234503	VACUSERA® 2,7 ml Coagulation 9NC %3,2 Sodium Citrate - Double Tube	42585	Evacuated blood collection tube IVD, sodium citrate
234504	VACUSERA® 4 ml Coagulation 9NC %3,2 Sodium Citrate	42585	Evacuated blood collection tube IVD, sodium citrate
434501	VACUSERA® 1 ml Coagulation 9NC %3,2 Sodium Citrate - Double Tube	42585	Evacuated blood collection tube IVD, sodium citrate
434502	VACUSERA® 1,8 ml Coagulation 9NC %3,2 Sodium Citrate - Double Tube	42585	Evacuated blood collection tube IVD, sodium citrate
434503	VACUSERA® 2,7 ml Coagulation 9NC %3,2 Sodium Citrate - Double Tube	42585	Evacuated blood collection tube IVD, sodium citrate
434504	VACUSERA® 4 ml Coagulation 9NC %3,2 Sodium Citrate	42585	Evacuated blood collection tube IVD, sodium citrate
234512	VACUSERA® 1,8 ml Coagulation 9NC %3,8 Sodium Citrate - Double Tube	42585	Evacuated blood collection tube IVD, sodium citrate
234513	VACUSERA® 2,7 ml Coagulation 9NC %3,8 Sodium Citrate - Double Tube	42585	Evacuated blood collection tube IVD, sodium citrate
234514	VACUSERA® 4 ml Coagulation 9NC %3,8 Sodium Citrate	42585	Evacuated blood collection tube IVD, sodium citrate
434512	VACUSERA® 1,8 ml Coagulation 9NC %3,8 Sodium Citrate - Double Tube	42585	Evacuated blood collection tube IVD, sodium citrate
434513	VACUSERA® 2,7 ml Coagulation 9NC %3,8 Sodium Citrate - Double Tube	42585	Evacuated blood collection tube IVD, sodium citrate
434514	VACUSERA® 4 ml Coagulation 9NC %3,8 Sodium Citrate	42585	Evacuated blood collection tube IVD, sodium citrate
234522	VACUSERA® 1,8 ml Coagulation 9NC CTAD - Double Tube	42569	Evacuated blood collection tube IVD, Citrat-Theophyllin-Adenosin-Dipyridamol (CTAD)
234523	VACUSERA® 2,7 ml Coagulation 9NC CTAD - Double Tube	42569	Evacuated blood collection tube IVD, Citrat-Theophyllin-Adenosin-Dipyridamol (CTAD)
434522	VACUSERA® 1,8 ml Coagulation 9NC CTAD - Double Tube	42569	Evacuated blood collection tube IVD, Citrat-Theophyllin-Adenosin-Dipyridamol (CTAD)
434523	VACUSERA® 2,7 ml Coagulation 9NC CTAD - Double Tube	42569	Evacuated blood collection tube IVD, Citrat-Theophyllin-Adenosin-Dipyridamol (CTAD)

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DEC_Blood Collection Tube,03,27.09.16

Product Code	Product Description	GMDN Code	GMDN Description
234601	VACUSERA® 1 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
234602	VACUSERA® 2 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
234603	VACUSERA® 3 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
234604	VACUSERA® 4 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
234605	VACUSERA® 4,5 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
235606	VACUSERA® 6 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
236609	VACUSERA® 9 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
434601	VACUSERA® 1 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
434602	VACUSERA® 2 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
434603	VACUSERA® 3 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
434604	VACUSERA® 4 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
434605	VACUSERA® 4,5 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
435606	VACUSERA® 6 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
436609	VACUSERA® 9 ml K2E / K2EDTA	43865	Evacuated blood collection tube IVD, K2EDTA
234611	VACUSERA® 1 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
234612	VACUSERA® 2 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
234613	VACUSERA® 3 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
234615	VACUSERA® 4,5 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA

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Product Code	Product Description	GMDN Code	GMDN Description
235616	VACUSERA® 6 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
236619	VACUSERA® 9 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
434611	VACUSERA® 1 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
434612	VACUSERA® 2 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
434613	VACUSERA® 3 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
434615	VACUSERA® 4,5 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
435616	VACUSERA® 6 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
436619	VACUSERA® 9 ml K3E / K3EDTA	47588	Evacuated blood collection tube IVD, K3EDTA
234623	VACUSERA® 3 ml K2E / K2EDTA & Gel	47587	Evacuated blood collection tube IVD, K2EDTA,gel
235625	VACUSERA® 5 ml K2E / K2EDTA & Gel	47587	Evacuated blood collection tube IVD, K2EDTA,gel
236628	VACUSERA® 8 ml K2E / K2EDTA & Gel	47587	Evacuated blood collection tube IVD, K2EDTA,gel
434623	VACUSERA® 3 ml K2E / K2EDTA & Gel	47587	Evacuated blood collection tube IVD, K2EDTA,gel
435625	VACUSERA® 5 ml K2E / K2EDTA & Gel	47587	Evacuated blood collection tube IVD, K2EDTA,gel
436628	VACUSERA® 8 ml K2E / K2EDTA & Gel	47587	Evacuated blood collection tube IVD, K2EDTA,gel
234702	VACUSERA® 2 ml FE / Sodium Floride & K3EDTA	58090	Evacuated blood collection tube IVD, K3EDTA sodium floride
234704	VACUSERA® 4 ml FE / Sodium Floride & K3EDTA	58090	Evacuated blood collection tube IVD, K3EDTA sodium floride
434702	VACUSERA® 2 ml FE / Sodium Floride & K3EDTA	58090	Evacuated blood collection tube IVD, K3EDTA sodium floride
434704	VACUSERA® 4 ml FE / Sodium Floride & K3EDTA	58090	Evacuated blood collection tube IVD, K3EDTA sodium floride

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Product Code	Product Description	GMDN Code	GMDN Description
233902	VACUSERA® 1,6 ml 4 NC / ESR Sodium Citrate	42585	Evacuated blood collection tube IVD, sodium citrate
233903	VACUSERA® 1,28 ml 4 NC / ESR Sodium Citrate	42585	Evacuated blood collection tube IVD, sodium citrate
234902	VACUSERA® 2 ml 4 NC / ESR Sodium Citrate	42585	Evacuated blood collection tube IVD, sodium citrate
433902	VACUSERA® 1,6 ml 4 NC / ESR Sodium Citrate	42585	Evacuated blood collection tube IVD, sodium citrate
434902	VACUSERA® 2 ml 4 NC / ESR Sodium Citrate	42585	Evacuated blood collection tube IVD, sodium citrate

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