

TEK-BAL TIBBİ CİHAZLAR

Maltepe Mah.Dokumacılar Sit.No:36

Zeytinburnu / İSTANBUL

TURKEY

Bischofshofen, 2019-12-20

Inspection report BI 23420

TEK-BAL TIBBİ CİHAZLAR

Validation according to EN 285 and EN ISO 17665

Ordered by:	TEK-BAL TIBBİ CİHAZLAR Maltepe Mah.Dokumacılar Sit.No:36 Zeytinburnu / İSTANBUL TURKEY		
Date of order:	2019-07-31		
Inspection order:	Thermoelectrical measuring, using the borderlines / requirements given in EN 285 and/or EN ISO 17665		
Inspection item:	Manufacturer:	TEKBAL Sterilizers	
	Device:	Steam Sterilizer (450 liter) STR-450 / SRN: 20190153	
Date of inspection:	2019-12-20	Inspection by:	Prof. Dr. med. H.-P. Werner; HygCen Austria GmbH
Inspection period / test period:	2019-07-31 – 2019-08-02		
Participants of the inspection:	Ms. Feltgen, HygCen Austria GmbH Mr. Bülent Deveci, UMS Medikal		
Inspection method / test method:	SOP 21-015 Thermoelectrical measuring, using the borderlines / requirements given in EN 285 and/or EN ISO 17665		

7 CONCLUSION

According to the results TEK-BAL/ STR: 450 can be confirmed, that the types / sizes of steam sterilizers tested are conform to EN 285 and/or EN 17665.

This is also valid for all types / sizes of steam sterilizers, build in the same way of the exemplary tested sterilizers, within the chamber sizes from 450 liter.

Archiving: A copy of this report is kept together with the raw data in the archive of HygCen Austria GmbH.

Note: The present inspection report refers exclusively to the conditions found during the inspection. Any duplication in extracts requires the written permission of HygCen Austria GmbH.



Prof. Dr. med. H.-P. Werner
Technical manager
Inspector



Monika Feltgen
Vice technical manager
Inspector

TEK-BAL TIBBİ CİHAZLAR
Maltepe Mah.Dokumacılar Sit.No:36
Zeytinburnu / İSTANBUL
TÜRKİYE

Akkreditierte
Inspektionsstelle nach
ÖNORM EN ISO 17020



Bischofshofen, 2020-05-10

Inspection report BI 24213 I
TEK-BAL TIBBİ CİHAZLAR
Steam quality test according to EN 285

Ordered by: TEK-BAL TIBBİ CİHAZLAR

Date of order: 05.03.2020

Inspection order: Steam quality test according to EN 285

Inspection item: Steam Sterilizer TEK-BAL STR 450
SRN: 20190153

Date of inspection: 10.05.2020 **Inspection by:** Monika Feltgen ;
HygCen Austria GmbH

**Inspection period /
test period:** 05.03.2020

**Participants of the
inspection:** Bülent Deveci; UMS Medikal Test

Inspection method: SOP 21-015
Steam Quality test with non-condensable gas, steam superheat, and
dryness tests in EN 285:2016

6 Conclusion

According to the results TEK-BAL STR 450 ; SRN: 20190153 can be confirmed, that the steam quality tested are conform to EN 285:2016.

Archiving: A copy of this report is kept together with the raw data in the archive of HygCen Austria GmbH.

Reference: The test results refer exclusively to the mentioned test piece. Extractions of this report only with a written permission of the HygCen Austria GmbH.

A handwritten signature in blue ink, consisting of a series of loops and a long horizontal stroke.

Prof. Dr. med. H.-P. Werner
Technical manager
Inspector

A handwritten signature in blue ink, featuring a stylized 'M' and a long, sweeping horizontal stroke.

Monika Feltgen
Vice technical manager
Inspector

LVT Test Laboratuvarları Ltd. Şti.

AB-0341-T

19-1507-
R1-N1-1

01-20

3/53

1. Numunelerin Tanımı : BUHAR STERİLİZATÖRÜ Definition of the Samples : STEAM STERILIZERS .

1.1 STR-450

(19-1507-R1-N1)

Numune Kabul Tarihi : 19.09.2019
Date of Receive
Numune Seri No : 20190153
Serial No
Beyan Gerilimi U_n : 380 V AC
Rated Operational Voltage
Beyan Akımı I_n : 40 A
Rated Current
Beyan Güç : -
Rated Power
Beyan Frekans f_n : 50-60 Hz
Rated Frequency

2. Deney Sonuçları Test Results

Deney sonuçları, müşteri tarafından laboratuvara teslim edilen ve sadece deneyi yapılan numunelere aittir.
The test results only belong to the tested sample(s) delivered to the laboratory by client.

Numune Sample	Uygulanan Deney Applied Test	Uygulanan Standartlar Applied standards	Sonuç Result
STR-450	Elektrostatik Boşalma Bağışıklık Deneyi (Electrostatic Discharge Immunity Test)	TS EN 61000-4-2	OLUMLU Passed
	Işıyan, Radyo Frekans, Elektromanyetik Alan, Bağışıklık Deneyi* (Radiated, radio- frequency, electromagnetic field immunity test)	TS EN 61000-4-3	
	Elektriksel Hızlı Geçici Rejim/Patlama Bağışıklık Deneyi (Electrical Fast Transient/Burst Immunity Test)	TS EN 61000-4-4	
	Ani Yükselmelere Karşı Bağışıklık Deneyi (Surge Immunity Test)	TS EN 61000-4-5	
	RF Alanlar Tarafından Endüklenen,İletilen Bozulmalara Karşı Bağışıklık Deneyi (Immunity to Conducted Disturbances Induced by Radio Frequency Fields)	TS EN 61000-4-6	
	Şebeke Frekanslı Manyetik Alan Bağışıklık Deneyi (Mains frequency magnetic field immunity test)	TS EN 61000-4-8	
	Gerilim Çukurları,Kısa Kesintiler ve Gerilim Değişimleri Bağışıklık Deneyi (Voltage Dips,Short Interruptions and Voltage Variations Immunity Test)	TS EN 61000-4-11	
	Bağlantı Ucu Bozulma Gerilimi (Conducted Emission)	TS EN 55011	
	Yayılım Bozulması (Radiated Emission)	TS EN 55011	
	Harmonikler (Harmonics)	TS EN 61000-3-2	
	Gerilim Dalgalanmaları ve Kırpışma (Voltage Variations and Flicker)	TS EN 61000-3-3	

* TS EN 61000-4-3 deneyi 1000MHz ile 2700MHz arası kapsam dışı olarak gerçekleştirilmiştir.



LVT Test Laboratuvarları Ltd. Şti.

AB-0341-T

19-1507-
R1-N1-2

01-20

3/127

1. Numunelerin Tanımı Definition of the Samples

BUHAR STERİLİZATÖRÜ STEAM STERILIZERS

(19-1507-R1-N1)

1.1

Numune Kabul Tarihi Date of Receive	:	19.09.2019
Numune Seri No Serial No	:	20190153
Tip Type	:	STR-450
Kutup Sayısı Number of Poles	:	3P
Beyan Gerilimi Rated Voltage	U_n	: 380 VAC
Beyan Akımı Rated Current	I_n	: 40 A Per Phase
Beyan Frekans Rated Frequency	f_n	: 50 Hz
Beyan Koruma Derecesi Rated Degree of Protection	IP	: 20
Numune Boyutları Dimensions of the Sample	mm	: -
Numune Ağırlığı Weight of the Sample	kg	: 1100
Sınıf Class	:	Class I
Cihaz – Malzeme Listesi Device – Component List	:	Bknz. Firma Dökümanları See Documentary of Client

2. Deney Sonuçları Test Results

Deney sonuçları, müşteri tarafından laboratuvara teslim edilen ve sadece deneyi yapılan numuneye aittir.
The test results only belong to the tested sample(s) delivered to the laboratory by client.

Numune Sample	Uygulanan Deney Applied Test	Sonuç Result
STR-450	TS EN 60601-1:2009 + A1:2014 + AC:2011 + A12:2015 + A1/AC:2014 (IEC 60601-1:2005/AMD1:2012/COR1:2014)	OLUMLU PASSED

3. Çevre Şartları Environmental Conditions

3.1 Ortam Sıcaklığı : (23±3) °C
Ambient Temperature

3.2 Ortam Nemi : (30±3) %Rh
Ambient Moisture

4. Deney Metodundan Sapma, Ekleme ve Çıkarmalar

: Deneyler; standart deney metoduna göre uygulanmıştır.
Tests were made according to the clauses of the relevant standards.

5. Şartnamelere Uygunluk (Gerekli Hallerde) Conformity to Specifications (If Necessary)