Test Laboratuvarları

LVT Test Laboratuvarları Ltd. Şti.

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KD-19-1576-R1-N1-4
11-19

DENEY RAPORU

Test Report

Müşteri *Client*	:	STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOM. İNŞ. GIDA SAN. ve DIŞ TİC. LTD. ŞTİ.
Adres *Address*	:	BAŞKENT ORGANİZE SANAYİ BÖLGESİ 18. CADDE NO: 43 MALIKÖY, SİNCAN / ANKARA
İmalatçı *Manufacturer*	:	STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOM. İNŞ. GIDA SAN. ve DIŞ TİC. LTD. ŞTİ.
Deney Numunesi *Test Sample*	:	SMB-DSD-300A
Marka *Trade Mark*	:	STERİLMED
Deney Metodu *Test Method*	:	TS EN 61010-2-040:2016 (IEC 61010-2-040:2015)
Deney Tarihi *Date of Test*	:	14.10.2019 – 25.10.2019
Toplam Sayfa Sayısı *Total Number of Pages*	:	39
Basım Tarihi *Date of Issue*	:	29.11.2019

Deney ve / veya ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri (talep halinde) ve deney metotları, bu raporun tamamlayıcı kısmı olan takip eden sayfalarda verilmiştir.

The test and / or measurements results, the uncertainties (if required) with confidence probability and test methods are given on the following pages which are part of this report.

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Date: 2024.02.29 17:03:19 EET
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Location: Moldova

Mühür *Seal*	Deney Sorumlusu *Person in Charge of Test*	Laboratuvar Müdürü *Head of Testing Laboratory*
	Abdurrahman YAMAN	Cahit GÖLKSEL

Rapor detaylarını karekod ile kontrol edebilirsiniz.
You can check the report details via QR code.

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İçindekiler **Sayfa**
Contents Page

1. Numunelerin Tanımı / *Definition of the Samples* — **BUHAR STERİLİZATÖRÜ** / *STEAM STERILIZERS*

1.1 SMB-DSD-300A **(KD-19-1576-R1-N1)**

Numune Kabul Tarihi *Date of Receive*		:	19.09.2019
Numune Seri No *Serial No*		:	SMB-DSD-300A-2019-012
Tip *Type*		:	SMB-DSD-300A
Kutup Sayısı *Number of Poles*		:	Three Phase
Beyan Gerilimi *Rated Voltage*	U_n	:	380
Beyan Akımı *Rated Current*	I_n	:	60A
Beyan Frekans *Rated Frequency*	f_n	:	50
Beyan Koruma Derecesi *Rated Degree of Protection*	IP	:	2X
Numune Boyutları *Dimensions of the Sample*	mm	:	-
Numune Ağırlığı *Weight of the Sample*	kg	:	-
Sınıf *Class*		:	Class I
Cihaz – Malzeme Listesi *Device – Component List*		:	Bknz. sf; 39 *See pg.*

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*
BUHAR STERİLİZATÖRÜ	TS EN 61010-2-040:2016 (IEC 61010-2-040:2015)	OLUMLU *PASS*

3. Çevre Şartları / *Environmental Conditions*

3.1 Ortam Sıcaklığı / *Ambient Temperature* : (22±3) °C

3.2 Ortam Nemi / *Ambient Moisture* : (40±3) %Rh

4. Deney Metodundan Sapma, Ekleme ve Çıkarmalar / *Deviations, Additions & Cutbacks from the Test Method* : 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)* :

6.	**Dağıtım Bilgileri** *Distrubition Information*	:	STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOM. İNŞ. GIDA SAN. ve DIŞ TİC. LTD. ŞTİ.
7.	**Açıklama** *Explanation*	:	-
8.	**Ölçüm Belirsizliği** *Uncertainty of Measurement*	:	Detaylar aşağıdaki tabloda verilmiştir. *The details are mentioned table below.*

Beyan edilen genişletilmiş ölçüm belirsizliği, standart belirsizliğin k=2 olarak alınan genişletme katsayısı ile çarpımı sonucunda bulunan değerdir ve % 95 oranında güvenilirlik sağlamaktadır.
The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement *multiplied by the coverage factor k=2 which for a normal distribution corresponds to a coverage probability of approximately 95 %.*

Deney bilgisi *Test details*	**Cihaz kodu** *Device code*	**Ölçülen değer** *Measured value*	**Ölçüm belirsizliği** *Measurement uncertainty*
Ambient Temperature	LC349	See Clause 3.1	%4,62
Sound Level Measurement	LC44	See Table 12.5.1	%0,31

9. Deney Uygulamaları:
Test Applications

TEST REPORT
IEC 61010-2-040
Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-040 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

Report Number.....:	19-1576-R1-N1-4
Date of issue.....:	29.11.2019
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Name of Testing Laboratory preparing the Report.....:	LVT TEST LABORATUVARLARI LTD. ŞTİ.
Applicant's name .....:	STERİLMED MEDİKAL ELEKTRİK ELEKTRONİK OTOM. INŞ. SAN. ve DIŞ TİC. LTD. ŞTİ.
Address.....:	BAŞKENT ORGANİZE SANAYİ BÖLGESİ 18. CADDE NO:43 MALIKÖY SİNCAN/ANKARA
Test specification:	
Standard .....:	IEC 61010-2-040: 2015-07 (Second Edition) for use in conjunction with IEC 61010-1:2010 (Third Edition)
Test procedure .....:	CB Scheme
Non-standard test method .....:	N/A
Test Report Form No. .....:	IEC61010_2_040B
Test Report Form(s) Originator.....:	VDE Testing and Certification Institute
Master TRF .....:	2015-09

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing CB Testing Laboratory.
The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Sterilmed® TIBBİ CİHAZLAR

STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOM. İNŞ. GIDA SAN. VE DIŞ TİC. LTD. ŞTİ.
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CE 2292

CERTIFIED ISO COMPANY — ISO 13485:2016

- Don't power on the device before you read the instructions!
- Must be serviced and operated by authorized personnel only.
- Please include information when ordering spare parts.

STEAM STERILIZER

Model	Serial No	Volume	Power	
SMB-DSD-300A	SMB-DSD-300A-2019-013	300 L	26 kVA	2019

WEEE Waste Recycling

IP2X Class I 3~

		AC Voltage	380 V	Frequency	50 Hz
	Serial No	Working Pressure	Working Temperature	Testing Pressure	Vacuum Pressure
Chamber	2019-11-H-01-01	2.7 bar	0-134°C	6.5 bar	70 mbar
Generator	2019-08-J-02-01	3.0 bar	0-144°C	9.0 bar	

F.08.06-0 Yayın Tarihi :27.09.2019

Test item particulars..... :	SMB-DSD-300A
Classification of installation and use ..... :	
Supply Connection ..... :	Three phase
..... :	
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement .....:	P (Pass)
- test object does not meet the requirement.....:	F (Fail)
Testing .....:	
Date of receipt of test item.....:	19.09.2019
Date (s) of performance of tests .....:	14.10.2019 – 25.10.2019

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
“(See Form A.xx)” refers to a table at corresponding IEC 61010-1 Test Report
“(See Form B.xx)” refers to a table appended to this report.

The Test Results presented in this Test Report relate only to the objected tested. This Test Report shall not be reproduced except in full without the written approval of the testing laboratory.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

General product information:

IEC 61010-2-40			
Clause	Requirement - Test	Result - Remark	Verdict
4	**TESTS**		P
4.4	Testing in SINGLE FAULT CONDITION		P
4.4.2.5	Motors	See below;	P
	if impractical to test in place, separate identical motor tested	(see Form A.1, and A.26B) Motor tested seperate from the EUT.	P
4.4.2.13	Interlocks		N
	tested without using toxic substances	(see Form A.1) No interlocks	N
4.4.2.101	Pressure controllers	No pressure controllers. Overpressure safety devices used.	N
	Pressure controllers overridden (except for overpressure safety devices complying with 11.7.4)	(see Form A.1)	N
4.4.2.102	Failure, or partial failure, of the MAINS supply	Test not conducted.	N
	Following tests have been conducted:	(see Form B.1)	—
	Operate at 90 % of RATED voltage for one cyle		N
	Operate at 110 % of RATED voltage for one cycle		N
	Set to 90 % of RATED voltage for 5 min		N
	reduced (gradually 10 V / min) to ..... :		N
	Reset to RATED voltage		N
4.4.2.103	Failure, or partial failure, of other supplies and services		N
	Each non-electrical and service supply interrupted or partial interrupted	(see Form B.1)	N

5	**MARKING AND DOCUMENTATION**		P
5.1.2	Identification	See below;	P
	The equipment marked with at least the following:		—
	a) name and address of the manufacturer	Sterilmed® TIBBİ GİMSİLER	P

	b) additional markings required by national and local regulations	No such additional marking used.	N
	name and address of the manufacturer's authorized representative		N
	c) equipment provide unique identifier (e.g. serial number)	SMB-DSD-300A-2019-013	P
	d) year and place of manufacturing; if different from manufacturer's address	Same.	N
	e) model identification	Model SMB-DSD-300A	P
	f) designated purpose of the equipment.	STEAM STERILIZER	P
5.1.101	Overpressure safety device		P
	Identification includes:		—
	Name of manufacturer.....:	AYVAZ	P
	Model number.....:	PKV-50	P
	If bursting disc marked with:		—
	Specified bursting pressure .....:	1.6MPA	P
	Associate temperature.....:	Max 200°C	P
5.1.102	PRESSURE VESSELS and shell boilers		N
	national and local regulations that may require additional markings considered		N
5.2	Warning markings		P
	Warning markings specified in 5.1.5.1, 5.1.5.2 c), 5.1.5.2 d), 5.1.8, 5.4.4 r), 6.1.2 b), 7.3.2, 7.102 b), 7.102 c), 9.1, 10.1, 13.2.2, and 14.103		—
	meet the following requirements:		—
	Warning and Caution symbols at least 10mm high.	>1mm	P
5.4.1	General		P
	Accompanying documents shall be marked with:		—
	- Date of issue, or	02.01.2017	P
	- Revision status and	EN 003	P
	- Provided with the equipment	Provided.	P
	aa) national and local regulations apply to the documentation		N
	bb) if hazardous substances handled in NORMAL USE, the documentation includes:	Normal use not involves the handling of a hazardous substance.	—
	-information of constitutes, and		N
	-correct storage, and		N

	-correct use, and		N
	-safe disposal		N
	Marking, information and language:	See below;	—
	1) comply with regulations applying in the country of intended use		P
	NOTE 2: ISO15223-2 offers guidance for equipment classified as a medical device.		—
	2) incude instructions for the disposal of the equipment, its accessories and its packaging	Waste disposal mentioned in clause 7 of manual.	P
	3) give due consideration to the technical knowledge, education and training of different OPERATOR categories	See user's manual.	P
	4) not contradict information contained in documentation.	Considered.	P
5.4.2	Equipement ratings	Not applicable.	N
	aa) RATED ranges of pressure and flow rates for each non-electrical supply		N
5.4.3	Equipment installation	See clause 5.2. of manual.	P
	Instructions including details for:		—
	a) location and mounting	See clause 5.2.3. of manual.	P
	b) space required for safe and efficient maintenance;	See clause 5.2.3. of manual.	P
	c) individual weights of principal heavy subassemblies;		N
	d) overall weight and floor loading requirements;		N
	e) unpacking and assembly instructions (see als 7.108)	See clause 5.1. of manual.	P
	f) MAINS supply requirements		N
	connection		N
	temperature RATING of cable		N
	g) PERMANENTLY CONNECTED EQUIPMENT:		—
	1) supply wiring requirements		P
	2) requirements for:	See clause 5.2.2. of manual.	—
	- external switch or circuit-breaker (see 6.11.3.1)		N
	- external overcurrent protection devices (see 9.6.1)		N
	- recommendation for placement of switch or circuit breaker near to the equipment		N
	h) ventilation requirements (see 11.101, 13.1.103.1, and 13.1.101)	See clause 5.1. of manual.	P

	i) drainage requirements (see 11.101)	See clause 5.2.1. of manual.	P
	j) protective earthing	See clause 5.2.2. of manual.	P
	k) sound level (see 12.5.1)	See seperate test report.	P
	l) requirements for special services (air, feed water, cooling liquid, etc.)		N
	m) requirements related to hazardous gas atmospheres (see 13.0)		N
	n) positioning of the equipment not difficult to operate disconnecting device	Position of disconnectiong device not conflicting.	P
	o) Hazardous substances:	No hazardous substances.	—
	- handling		N
	- containment		N
	- additional equipment is required for control of emissions (see 13.1)		N
	p) HAZARDS caused by:	No such hazards.	—
	- liquids or		N
	- hot items falling from the equipment (see 9.1)		N
	q) requirements for material used		N
	- in the installation of the equipment		N
	- which may come in contact with sterilant (see 13.1.103.4 and 13.2.101)		N
	r) instructions for ambient illumination (see 11.102)		P
	NOTE Guidance on lighting is offered in ISO12100-2 and EN1837		—
	s) instructions relating to heat emission		N
5.4.3.101	Special systems	No special systems required.	N
	Installation instructions including details for:		—
	a) non-recirculating ventilation system for room (see 13.1.103.3)		N
	min. 10 air changes per hour……..:		N
	b) if toxic sterilant used:		—
	protection against HAZARDS arising from room ventilation failure (see 13.1.103.3)		N
	c) non-recirculating local exhaust system to remove fugitive emissions (see 13.1.101.4)		N

	d) drainage system (see 13.1.101.3)		N
	e) venting system for the drain (see 13.1.101.3)		N
	f) CHAMBER exhaust system (see 13.1.101.2)		N
	g) system to control escaping biological emissions (see 13.1.104)		N
	h) any other non-electrical supplies		N
	including prevention of back syphonage		N
5.4.4	Equipment operation		P
	a) identification of operating controls and	See clause 5.5. of manual.	P
	their use in all operating modes;		P
	b) positioning for disconnection	Position of disconnectiong device not conflicting.	P
	c) accessories and other equipment:		—
	including details for:	See clause 4.1.28. of manual.	—
	interconnection		P
	suitable accessories		P
	detachable parts		P
	special materials		P
	d) specification of limits for intermittent operation		P
	e) an explanation of symbols related to safety which are used on the equipment (see 5.2)	See clause 5.5.4. of manual.	P
	f) instructions for cleaning (see 11.2)	See clause 6.2. of manual.	P
	g) measures to make equipment safe after incomplete OPERATION CYCLE	See clause 5. of manual.	P
	h) use of lockable door closure prevention device (see 7.102.b)	See clause 5. of manual.	P
	i) safe access to LOAD in CHAMBER in case of failure addressed to RESPONSIBLE BODY (see 13.1.102)	See clause 2.3. of manual.	P
	j) actions in case of a malfunction including fault diagnosis	See clause 2.3. of manual.	P
	k) loading procedure	See clause 5. of manual.	P
	l) safe disposal of parts as:		—
	detergent containers		N
	sterilant containers		N

	parts contaminated by pathogenic material	All materials used in packaging are non-polluting. Wooden parts are not chemically processed unless specially requested.	N
m)	testing the function of critical safety devices (see 11.7.4)	See clause 4.1.21. of manual.	P
n)	handling of substances involved in NORMAL USE:		—
	correct use		N
	safety provisions		N
	methods of safe handling before disposal		N
	recommendations on disposal		N
o)	methods of reducing burn HAZARDS from surfaces permitted to exceed temperature limits	Safety instructions and warning signs used.	P
p)	guidelines to follow in case of emergency in which eye, skin contact or inhalation could occur		N
	guidelines prominently displayed on or near the equipment		N
q)	Safely replenishing containers for dosing chemicals (see 13.102)		N
r)	Appropriate warning stating types of LOAD which may be used		N
s)	Consumable materials:		—
of	details of HAZARDS arising from introduction incorrect quantities consumable materials		N
	procedures and details of protection to minimise such HAZARDS		N
t) instructions	identification of residual risks and on necessary protective procedures (see clause 17)	See risk assesment.	P
5.4.5	Equipment maintenance and service	See clause 6. of manual.	P
	Instructions provide sufficient details to:		—
	- permit safe maintenance and		P
	- inspection and		P
	- ensure continued safety of the equipment after the maintenance and inspection procedure		P
	Instructions include:		—

	a) details of maintenance on parts subjected to wear and tear if failure could lead to a HAZARD		N
	b) inspection and replacement of hoses and liquid containing parts if their failure could lead to a HAZARD		P
	c) safety devices fitted:		—
	settings and		P
	replacement procedures		P
	d) procedure for making the equipment safe prior to maintenance.		P
	e) maintenance schedules and repair procedures, including	See clause 6.4. of manual.	P
	ambient lighting level (see 11.102) and		P
	special precautions to protect against HAZARDS during repair		P
	f) methods of safe handling and disposal for parts containing or contaminated by toxic and/or pathogenic material	No toxic and pathogenic material.	N
	g) specific battery type for equipment using replaceable batteries		N
	h) RATING and characteristics of replaceable fuses		N
	i) a list of parts (if any):		—
	restricted to examination, and / or		N
	supplied by the manufacturer or manufacturer's agent		N
	j) RESIDUAL risks (see clause 17) and	See risk assesment.	P
	protective measures for these RISKS		P
	k) Verification of the safe state after repair		P
5.4.101	OPERATOR training		
5.4.101.1	Instructions include statement for RESPONSIBLE BODY to ensure that OPERATORS are adequately trained:	Service and maintenance will be certainly performed by a qualified and authorized service engineer of authorized dealer who was trained by STERILMED.	—
	a) in operating or maintaining the equipment		N
	b) if exposure limits (i.e. STEL or LTEL) or		N

	permissible working environmental concentration limits (see note to 13.1), could exceeded in NORMAL USE		N
	This instructions includes information about:		—
	- relevant health HAZARDS		N
	- national regulations		N
	- methods for safe use		N
	- leak detection methods		N
	c) Regular training for all personnel concerned with operation or maintenance including:		—
	Emergency procedures for any toxic, flammable, explosive or pathogenic material released into environment,		N
	attendance records maintained,		N
	evidence of understanding demonstrated		N
5.4.101.2	Procedures for potentially hazardous actions		P
	Safety procedures specified for any hazardous action to be carried out by operator	See manual.	P
	Statement that RESPONSIBLE BODY must provide OPERATORS training in this procedures		P

6	**PROTECTION AGAINST ELECTRIC SHOCK**		P
6.2.2	Examination		P
	FIXED EQUIPMENT and equipment with a weight more than 80 kg:		—
	- not tilted or moved to check the bottom		P
	- test finger applied in any part of the bottom can be reached	The test finger applied to any part of the bottom that can be reached when the equipment is installed according to the manufacturer's instructions.	P

7	**Protection against mechanical HAZARDS and against HAZARD related to mechanical functions**		P
7.1	General		P
	Conformity is checked by 7.2 to 7.107		P
7.4	Stability		P
	aa) Horizontal door supporting the LOAD withstand 1.2 times of the heaviest RATED LOAD	Doors can be opened vertically.	N

7.5.101	Transfer of LOADS into and out of the CHAMBER		P
	means to protect OPERATOR against mechanical hazard during transfer		P
	means to locate and retain the LOAD and its carrier in the correct position		P
	means to prevent sliding shelf tilting or disengaging		P
	force required for loading / unloading does not exceed 250 N	(see Form B.2) The force required by an OPERATOR to put the LOAD into the CHAMBER or remove it from the CHAMBER not exceed 250 N.	P
7.101	Doors, conveyors, etc.		P
	No hazard is caused in NORMAL or SINGLE FAULT CONDITION by:	No hazard coused in normal and single fault conditions above.	—
	a) mechanism to open, close or retain door		P
	b) wear on threaded parts		N
	c) residual movement of:	(see Form B.3)	P
	1) operation of emergency shut-down device		P
	2) loss of power		P
	3) component failure		P
	4) removal of an obstruction		P
	d) parts driven by power or stored energy	(see Form B.3)	P
7.102	Access to the CHAMBER		P
	Access not possible during OPERATION CYCLE if could cause to a HAZARD	Accessing to the chamber during operation permitted.	P
	Means provided to prevent:		—
	a) starting of the operation cycle if OPERATOR is inside		P
	b) door closing (if fitted) if OPERATOR is inside		P
	The means shall be:		—
	- lockable by dedicated key or TOOL or other mechanism, and		P
	- manufacturer's instructions shall specify that the OPERATOR must retain the key or TOOL while inside the CHAMBER, and		P
	- A warning marking (see 5.2) on the equipment clearly visible to the OPERATOR:		—
	- instruction for the OPERATOR to lock the means and		P

	- to retain the locking key, or TOOL at all times		P
	Hot liquid remaining in CHAMBER does not cause a hazard in NORMAL CONDITION or		P
	- a warning is kept in manufacturer's instructions and		P
	- a warning marking provided (see 5.2)		P
	In SINGLE FAULT CONDITION no HAZARD caused by liquids and steam when the door is openend or at the attempt to open it		P
7.103	Prevention of entry of gas, etc.	No entry of gas, etc.	N
	until the door is closed and secured, an Interlock is provided to:		—
	- prevent entering or generating of sterilant gas, carrier gas, steam or others in the CHAMBER and		N
	- all pressure retaining parts are engaged		N
7.104	Prevention of new OPERATING CYCLE		P
	Start of a new OPERATING CYCLE is not possible, if hazards arising of a failure in:		—
	a) door operating system		P
	b) LOAD transport system		P
	c) exhaust system		P
	d) any other device (e. g. timer or sensor)		P
	e) operation of the emergency shut-down device		P
7.105	Pressure-retaining parts of a door		N
	Interlock prevents release of door until CHAMBER is vented to atmospheric pressure		N
7.106	Doors of equipment for use with fluids in containers		N
	Door locked until:	(see Form A.26A)	—
	temperature of the LOAD and fluid in the CHAMBER is below boiling point at ambient pressure		N
	Equipment designed to process fluids in sealed unvented containers:		—
	- incorporate additional controls to keep door locked until the temperature of fluid inside the containers at athmospheric pressure has fallen to:		N
	- 20 K below boiling point of water for glass containers, or	(see Form A.26A)	N
	- 10 K below boiling point water for flexible containers	(see Form A.26A)	N

	Means provided to compensate the reduced boiling point at increased alstitude		N
	Temperature sensing of fluids never based on sensing a single container.		N
7.107	Double-ended equipment		P
	In NORMAL USE opening or closing of the door at remote end of CHAMBER not possible for the OPERATOR	It is not possible during normal use for an operator to open or close a door at the end of the chamber remote from the operator.	P
	Except for maintenance, opening of both doors at same time is prevented	Unable to open both doors at the same time in double door	P
	Opening of the door at remote end not possible if the conditions inside the equipment could cause a HAZARD		P
7.108	Transport and packaging		P
	Packaging fitted with, or accept attachments for easily connection to standard lifting equipment	See clause 5.2.1 of manual.	P
	Equipment and equipment parts packed in a manner that:		—
	- all parts of the equipment remain in position and stable, and		P
	- no HAZARD is caused		P
	Outside of the packaging marked with instructions for:		—
	- handling,		P
	- transport,		P
	- storage,		P
	- environment,		P
	- unpacking.		P
7.109	Guards and panelling		P
	removal or opening of a guard or panel require the use of a tool (see 14.102)		P
	If a personal access is provided in a panel, this access:		—
	- not less than 500 mm wide and 1500 mm high,		P
	- free from obstruction and		P
	- require the use of a TOOL.		P
	Fixings for attaching guards and panels shall remain attached to either the guard, or panel, or to the structure of the equipment.		P

7.110	Emergency shut-down device	See below;	P
	operated by easily reached and prominently placed push button or other actuator		P
	The shutdown device:		—
	a) not disconnect auxiliary circuits necessary for protection against HAZARD		P
	b) disconnect accessories necessary for the correct function of the equipment and		P
	which if disconnected separately could cause a HAZARD		N
	Installation instructions specify requirements for the interconnection of accessories necessary for the correct function of the equipment.		N
	If a mechanical HAZARD could occur, there shall be an actuator:		—
	- placed within 1 m of the hazardous moving part	No hazardous moving part.	N
	- designed to withstand a force of 250 N sustained for a minimum period of 0.75 s		N
	Shutdown device operates automatically if power supply to any door or conveyor is interrupted.		P
	While emergency shutdown device is in operation:		—
	1) residual movement of powered part does not cause a HAZARD		P
	2) potentially hazardous parts returned to safe state		P
	parts included to control compressed air, steam, liquids and contaminated materials		P
	Interlock system prevents restoration of normal operation until hazardous conditions are eliminated	No interlocks.	N
	Resetting the emergency shut-down device possible only with a key, code or other means or	With key.	P

9	**PROTECTION AGAINST THE SPREAD OF FIRE**		P
	If hot items fall from the equipment:		—
	Equipment not to be placed on surfaces which could cause a fire or fume, therefore		P
	- Warning provided, and	See clause 5.1 of manual.	P
	- included instruction manual		P
9.5.101	Requirements for equipment containing or using flammable gases	The EUT not containing flammable gas.	N
	see 11.7.4. d), 11.105 g), 13.2.102.1 to 13.101.6		N

10	**EQUIPMENT TEMPERATURE LIMITS AND RESISTANCE TO HEAT**		P
10.1	Surface temperature limits for protection against burns		P
	For hot items falling outfrom the equipment, see Clause 9.1	See separate test report and the form.	P
	If easily touched heated surfaces are necessary for functional reasons:	(see Form A.26A)	—
	- they are permitted to exceed the values of table 19 in NORMAL CONDITION and		—
	- to exceed 105°C in SINGLE FAULT CONDITION		—
	only if:		—
	- they are recognizable as such by appearance or function or	Not exceeded.	N
	- are marked with symbol 13 of Table 1 (see 5.2).		N
10.3	Other temperature measurements	No need for additional measurements.	N
	Additional temperatures are within the limits:		—
	In NORMAL CONDITION:	(see Form A.26A)	—
	aa) LOAD and fluid in the CHAMBER (7.106 a))		N
	bb) Fluid in sealed unvented containers (7.106 b))		N
	In NORMAL CONDITION and SINGLE FAULT CONDITION:	(see Form A.26A)	—
	cc) CHAMBER wall (10.5.101)		N
	dd) material (10.5.101)		N
	ee) Parts contacted by sterilant (13.2.102.2)		N
10.5.101	Other materials	Observed.	P
	Tempertures of materials not result in deterioration of materials performance in NORMAL CONDITION and SINGLE FAULT CONDITION	(see Form A.26A)	

11	**PROTECTION AGAINST HAZARDS FROM FLUIDS**		P
11.1	General		P
	Pathogenic substances (13.1.104)	No pathogenic substances.	N
	Chemical dosing (13.102)		N
11.7.2	Leakage and rupture at high pressure	See sub-clause 14.101.	P
	PRESSURE VESSELS and shell boilers meet the requirements of 14.101		P
11.7.4	Overpressure safety device	(see Form B.4)	P

	If maximum working pressure will exceeded, the:		—
	- Overpressure safety device fitted as specified in ISO 4126-1, and shall		P
	- set to operating pressure less than maximum working pressure, and shall		P
	- ensure that 110 % of maximum working pressure does not exceeded.		P
	The overpressure safety device shall:		—
	- not operate in NORMAL CONDITION, and		P
	- fullfill the following requirements:		—
	a) connected as close as possible to the parts to be protected		P
	b) installed in accordance to manufacturers instructions, and		P
	provide easy access for inspection, maintenance and repair		P
	c) Adjustment possible only by the aid of a TOOL		P
	d) Location of discharge opening		P
	e) no shut-off valve located between overpressure safety device and parts to be protected		P
	f) Fluid is unlikely to accumulate seat of valve		P
	g) Drain connection located at lowest position		P
	not cause a HAZARD		P
	h) Constructed of materials not be degraded to cause a HAZARD		P
	i) Marked according 5.1.101		P
	Bursting disc only used in combination with overpressure safety device		P
	Bursting disc is conform with ISO 4126-2		P
11.101	Discharge to atmosphere	No discharge to atmosphere.	N
	Discharge of pressure venting does not cause a HAZARD		N
	Discharge pipe:		—
	- has a continous fall to its outlet; or		N
	- automatic drain provided at relevant locations; or		N
	- specified in manufacturer`s instructions (see also 11.7.4 g))		N
	Discharge released inside equipment:		—

	- no pressure built up during ventilation		N
	- no HAZARD occurs from venting or discharge		N
11.102	Instruments and indicating devices	See below;	P
	Indication provided if necessary to protect against a hazard		P
	a) CHAMBER pressure	Inspected.	P
	b) Jacket pressure	Inspeced.	P
	c) OPERATING CYCLE counter	Visually inspected.	P
	d) current stage of the OPERATING CYCLE	Visually inspected.	P
	e) failure or partial falure of safety-related supplies		P
	f) line pressure for sterilant or chemical supply		N
	g) detection of leaks (see 13.1.103.1 a))		P
	h) water pump pressures	Inspeced.	P
	i) vapor condenser temperature	Inspeced.	P
	j) operating temperature	Inspeced.	P
	Redundancy shall be provided to assure that the OPERATOR receives sufficient information to avoid a HAZARD, even in SINGLE FAULT CONDITION		P
	During operation by a maintenance person		—
	- safety related devices easily seen by OPERATOR		P
	- Readable from 1 m distance		P
	- at illumination level in the range of 215 lx (± 15 lx) to 1500 lx (± 15 lx).		P
11.103	Protection of hot and cold water services		P
	Means provided conform with relevant requirements of IEC 61770	(see Attachment)	P
	National and local regulations considered.		P
	If provided by RESPONSIBLE BODY stated in instructions		P
11.105	Equipment with inflatable or pressure activated seals		N
	Means provided include the following:		—
	a) OPERATING CYCLE stops		N
	b) audible or visible alarm signal as fault indicator		N
	c) door remains closed		N
	d) supply of sterilant, disinfectant, steam, water or air into the CHAMBER interrupted		N

	e)	local exhaust ventilation		N
	f)	Sterilant gas:		N
		Source is isolated by automatic operated valve		N
		Complete system evacuated to discharge pipe		N
	g)	In case of flammable sterilant, complete system is purged with air or inert gas		N

12	**Protection against radiation, including laser sources, and against sonic and ultrasonic pressure**		N
12.3	Optical radiation	No radiation.	N
	unintentional escape of radiation at equipment provided with lamp or lamp systems emitting:		—
	ultraviolet radiation, or		N
	visible radiation, or		N
	infrared radiation, including light emitting diodes		N
	except for sources according Table 101……:		—
	assessed according IEC 62471, Risk Group……:	(see Attachment)	—
	labelled according IEC TR 62471-2	(see Photo Documentation)	N
	Accompanying documents contain:		—
	- protective measures,		N
	- restrictions on use		N
	- conditions of use of Table 102.		N
12.5	Sonic and ultrasonic pressure		P
12.5.1	Sound level		—
	no hazardous noise level produced, or		N
	maximum sound pressure level measured		—
	- at operator's position in NORMAL USE dB(A)……:	(see Form B.5)	P
	- at a distance of 1 m from the ENCLOSURE dB(A)….:	(see Form B.5)	P
	Exceptions:		—
	- sound from alarms		N
	- sound from parts remote from the equipment		N
	Hazardous sound pressure level described at the instructions.		N
	Installation instructions specify, how the RESPONSIBLE BODY can ensure that:		—

	- sound pressure level from equipment, will not reach a value that could cause a HAZARD after installation		N
	1) Identify readily available and practicable protective materials or		N
	measures which may be used		N
	2) sound pressure level measured in NORMAL USE		N
	- at the OPERATOR'S position and		N
	- at a point 1m from the ENCLOSURE in a location that has the highest sound pressure level		N

13	**PROTECTION AGAINST LIBERATED GASES, SUBSTANCES, EXPLOSION AND IMPLOSION**		N
13.1	Poisonous and injurinous gases and substances		N
	Dangerous amounts of such gases not liberated in NORMAL and SINGLE FAULT CONDITION		N
	If potentially-hazardous substances are liberated, the OPERATOR shall not be exposed to a quantity of the substance that could cause harm		N
	Discharge is not considered to be liberation of hazardous substances		N
	Risk assessment carried out if leakage could cause a toxic or explosive atmosphere in NORMAL CONDITION and in SINGLE FAULT CONDITION.:		—
	For CHAMBER access during OPERATING CYCLE, see 7.102 a)		—
	For preventing the start of a new OPERATING CYCLE, see 7.104		—
	For fire HAZARD from hot items falling out of equipment, see clause 9 (3).		—
13.1.101	CHAMBER discharge systems		N
13.1.101.1	Discharge from the CHAMBER		N
	Does not cause a HAZARD		N
13.1.101.2	Failure of CHAMBER exhaust system		N
	If a HAZARD could arise:		—
	- indicated by audible or visible alarm signals, independent from MAINS SUPPLY		N
	- emergency power system provided, if a failure in mains supply occure		N
	During a failure in CHAMBER exhaust system:		—
	- start of an OPERATING CYCLE prevented or		N

	- access to LOAD prevented		N
13.1.101.3	Protection from gases liberated from a drain		N
	Discharge from CHAMBER does not cause a HAZARD		N
	Installation instructions include statement for venting to a safe place		N
13.1.101.4	Local exhaust ventilation		N
	Means provided to connect to local exhaust system		N
	Installation instructions shall warn the RESPONSIBLE BODY that:		—
	a) additional local exhaust ventilation may also be required in storage areas for sterilant gas;		N
	b) the discharge from a local exhaust ventilation system is located so as not to cause a HAZARD.		N
13.1.102	LOAD access after fault		N
	Instructions for safe access to load after a fault provided		N
13.1.103	HAZARDS arising from the use of toxic sterilant		N
13.1.103.1	CHAMBER leakage		N
	If a HAZARD could arise:		—
	OPERATING CYCLE includes leakage check before sterilant gas is admitted to CHAMBER		N
	Equipment reverted to safe condition in case of hazardous leakage		N
	Non-return valve provided to prevent the escape of toxic sterilant gas for equipment operating above atmospheric pressure		N
13.1.103.2	Protection against gases liberated from the LOAD		N
	Door locked until sterilant concentration is reduced to safe level for OPERATOR .....:		N
	manufacturer shall advise the RESPONSIBLE BODY of any change required to take account of the very different gas absorption characteristics of materials processed. ..... :		N
13.1.103.3	Failure of room ventilation system		N
	If room ventilation is required to prevent a HAZARD:		—
	a) the equipment go into safe state		N
	b) start of a new OPERATING CYCLE is prevented		N
	c) indicated by both audible and visible alarm signal		N
13.1.103.4	Materials in contact with sterilant		N

	Materials in contact with sterilant:		—
	- not react with sterilant or carrier gas		N
	- not lead to a leakage in sufficient quantity		N
	Instructions include:		—
	- advise that the material used in the installation must not react with sterilant and carrier gas		N
13.1.104	Pathogenic substances		N
	Emission of aerosols or fluids do not cause a HAZARD:		—
	- in NORMAL CONDITION, or		N
	- in SINGLE FAULT CONDITION.		N
	Installation instructions include:		—
	additional means required to control emissions		N
13.2	Explosion and implosion		N
13.2.101	Materials in contact with sterilant		N
	Materials in contact with sterilant not reacting with sterilant or carrier gas, causing:		—
	- change in pressure resulting in explosion or implosion		N
	Statement included in instructions		N
	Attention paid for selection of material:		—
	- for effects of galvanic attack		N
	- for different rates of expansion		N
	Alloy with more than 65% mass fraction of copper not used		N
13.2.102	Explosion, implosion and fire of toxic gas STERILIZERS		N
13.2.102.1	Flammable sterilants		N
	Equipment using flammable sterilant, provide no source of ignition:		—
	- inside the CHAMBER,		N
	- inside its sterilant containers,		N
	- inside its exhaust pipings		N
	Protection in NORMAL and SINGLE FAULT CONDITION if mixture with air during process:		—
	Concentration reduced to below flammable limit before air is admitted at end of OPERATING CYCLE		N

	OPERATING CYCLE ensures prevents processing of next step of sterilization cycle in case of fire or explosion HAZARD		N
	CHAMBER exhaust system complies with 13.1.101.2		N
13.2.102.2	Heating of flammable liquid sterilant		N
	Steriliant containers not subjected to direct heating		N
	Flammable or explosive liquids not in direct contact with electrical heating element		N
	Temperature of parts in contact with sterilant:	(see Form A.26A)	—
	not cause fire or explosion HAZARD in NORMAL and SINGLE FAULT CONDITION		N
13.101	Other HAZARDS araising from the use of toxic sterilants		N
13.101.1	Opening or disconnecting a sterilant supply system		N
	Means provided to prevent HAZARDS (e. g. purging)		N
13.101.2	Gas blending		N
	No toxic, fire or explosion HAZARD occurs as result from incorrect mixing in NORMAL and SINGLE FAULT CONDITION	(see Form B.1)	N
13.101.3	Sterilant supply		N
	Additional controls or mechanisms provided to interrupt sterilant supply to CHAMBER		N
	Means provided for safe dispensing, connecting and positioning of containers		N
13.101.4	Supply from sterilant cartridges		N
	Means prevent access during OPERATING CYCLE		N
13.101.5	Isolation of any part of sterilant supply system		N
	Overpressure safety device complies 11.7.4		N
13.101.6	Failure of sterilant supply control system		N
	Indicated by visible alarm signal		N
	Equipment in safe state		N
	Initiating OPERATING CYCLE not possible		N
13.102	Chemical dosing systems		N
	Means provided to replenish containers without creating a HAZARD		N

14	**COMPONENTS**		P
14.101	PRESSURE VESSELS and shell boilers		P

	Comply with applicable national PRESSURE VESSEL regulations, codes or standards……..:		N
	or		—
	meet the requirements of clause 11.7	Comply.	P
14.102	Access ports		P
	If opened and closed by OPERATOR without the use of a TOOL:	Not likely.	—
	opening prevented, if HAZARD exists		N
14.103	Control systems	Controlling depends on computerised system. No such hazard.	P
	If OPERATOR setting causes a HAZARD, a warning marking is provided (see 5.2)		N
	Automatic controller provided with system to control access to system functions		N
	The following functions are protected by increasingly severe constrains [examples in brackets]:		—
	a) Initiating of OPERATING CYCLE [operator]		P
	b) Selection of OPERATING CYCLE [OPERATOR / SUPERVISORS]		P
	c) Changing OPERATING CYCLE parameters [supervisors]		P
	d) Manual advance through OPERATING CYCLE [suitable trained technicians]		P
	e) Maintenance [suitable trained technicians]		P
	f) changing OPERATING CYCLE programme [manufacturer or agent]		P
	Except for a) and b), above functions require the use of different keys, codes or other equivalent means.		P
	Higher-level TOOLS, keys or codes may allow access to lower levels.		P
	Termination of OPERATING CYCLE does not require special TOOL, key or code		P
	Disabling of safety devices prevented during NORMAL USE even in manual advance or automatic mode		P
	Selection of manual mode disables automatic controller		P
14.104	Microprocessors		P
	Failure of safety-related microprocessors does not cause a HAZARD	No safety-related mcu.	N

	Loss of processor memory battery power does not lead to a HAZARD	(see Form B.1)	P
14.105	Asbestos		N
	No parts of asbestos used		N

4.4	TABLE: Testing in single FAULT CONDITION – Results			Form B.1	P
Test subclause	Fault No.	Fault description	Td 4.4.3 (NOTE)	How was test terminated Comments	Meets 4.4.4
14.2.1	1	Motor prevented from starting.		Motor tested outside of equipment. Prevented from starting for 10 sec. after the test the circuit breaker triggered.	P

NOTE Td = Test duration in h:min:s
Record temperature tests on Form B.4.
Record in the comments column for each test whether carried out during or after SINGLE FAULT CONDITION.

Supplementary information:

7.4.101	TABLE: Transfer of LOADS into and out of the CHAMBER	Form B.2	P
Description where test applied	Force (N)	Remark	Verdict
Chamber	250	No damage	P

Supplementary information:

7.101	TABLE: Doors, conveyors etc.			Form B.3	P
Description where test applied		Force (N)	Interlocked Yes / No	Remark	Verdict
Mechanism used to open, close, retain the door		150	N	No damage.	P
Supplementary information:					

7.101 d)	TABLE: Residual movement			N
Description where test applied		Speed cm / s	Distance moved (cm)	Verdict
Supplementary information:				

11.7.4	**TABLE: Overpressure safety device**	**Form B.4**	N

Part	Maximum permissible working pressure MPa	Pressure inside PRESSURE VESSEL MPa	Safety device operating YES / NO	Remark

Supplementary information:

12.5.1	TABLE: Sound level	Form B.5	P

Locations tested	Measured maximum sound level dB(A)	Remarks / Comments
At operator's normal position and at 1 m distance	71.6	Comply.
a)		
b)		
c)		
d)		
e)		
f)		

Supplementary information:

SP	TABLE: Additional or special tests conducted	N

Clause and Name of Test	Test type and condition	Observed results

Supplementary information:

	TABLE 1: - List of components and circuits relied on for safety	See Documentary of Client	P

Object / Part No.	Application/function	Manufacturer / trademark (NOTE 1)	Type / model	Technical data (NOTE 2)	Standard (Edition / Year)	Mark(s) of conformity evidence of acceptance (NOTE 3 and 4)

NOTE → 1 List all different manufacturers of the above components
→ 2 May include electrical, mechanical values
→ 3 List licence no or method of acceptance
→ 4 asterisk indicates mark assuring agreed level of surveillance

10. Deney ve Ölçüm Bilgileri:
Test And Measuring Arrangement

Cihaz *Device*	**İmalatçı** *Manufacturer*	**Seri No. / Kod** *Serial No / Code*	**Sertifika No** *Certificate No*	**Kalibrasyon Bitiş Tarihi** *Calibration Due Date*
Temperature & Humidity	CEM	LC349	19SC0067	01/2020
Decibelmeter	TES-1352A	LC44	18601	09/2021
Caliper	ACCUD	LC365	09BY0087	01/2020
Newtonmetre	NK-500	LC204	1920913	09/2020

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11. Deney Osilogramları:
Test Oscillograms

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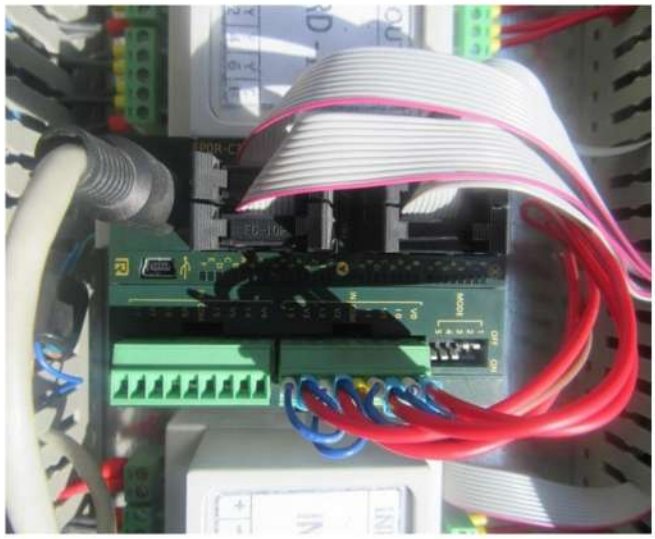
12. Deney Fotoğrafları:

Test Photographs

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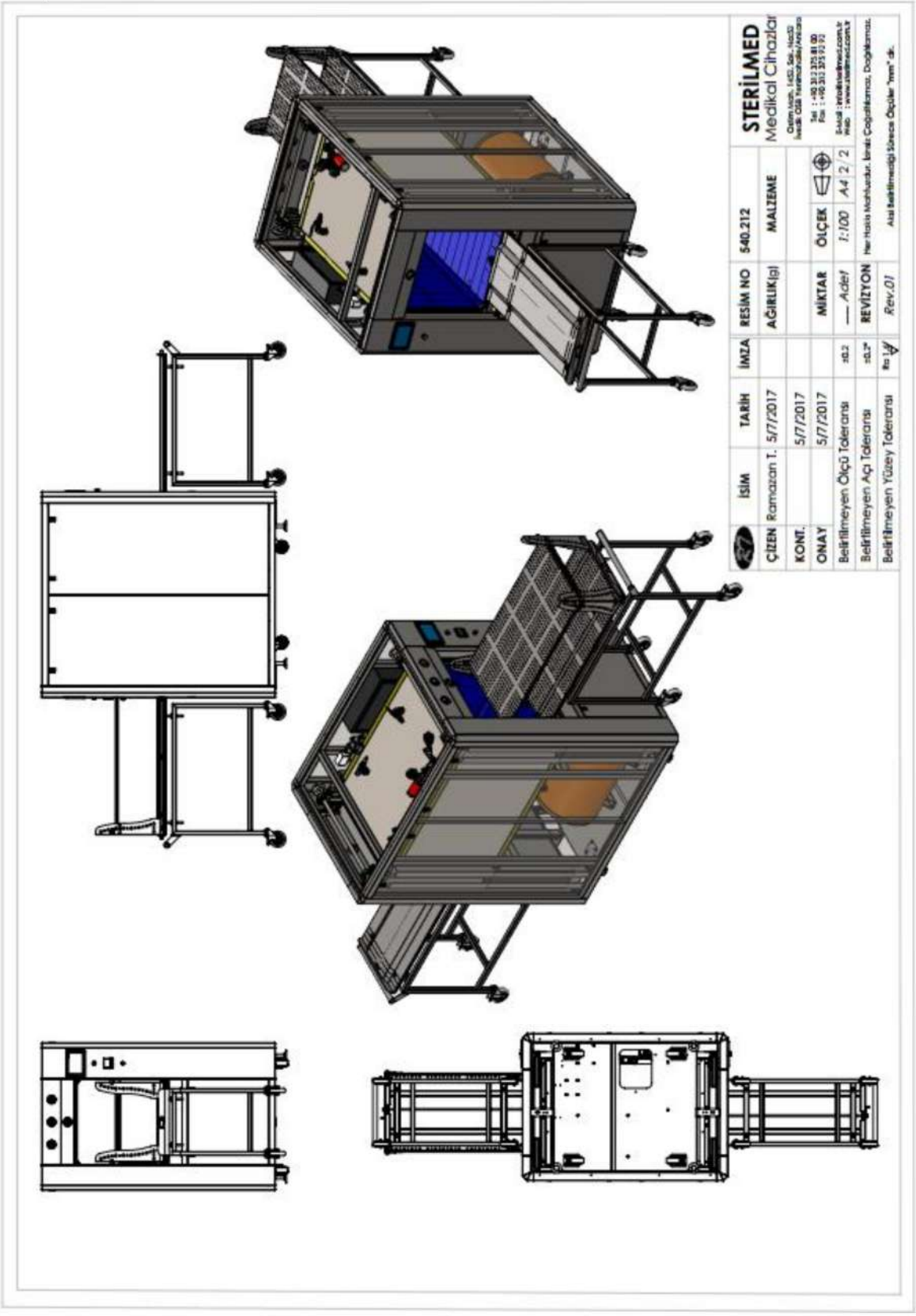
13. Firma Dokümanları:

Documentary of Client



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KRİTİK KOMPONENT LİSTESİ

SN	PARÇA ADI	MALZEME	SERTİFİKA	ÜRETİCİ	TEDARİKÇİ
1	Sıvı Seviye Rölesi (SSR)	3UG4501-1AW30	CE	SİEMENS	BEHA ELEKTRİK
2	Matsushita Nais FPO C32CP PLC	FPOC32CP	CE	PANOSONIC	ENKOSİS
3	Easy View MT6070 Operatör Paneli	MT6070	CE	VEINTEK	ENKOSİS
4	Basınç Sensörü	Type 401001	CE	JUMO	JUMO
5	Sıcaklık Sensörü PT100	902210	CE	JUMO	JUMO
6	-1...5 bar Manometre	MG063DRM1	CE	PAKKENS	HİDTEK/HİDROKONTROL
7	Vakum Pompası 3 faz	MB128	CE	AZİM POMPA	AZİMPOMPASI
8	Su Pompası	PM50	CE	WATER SOUND	BEHA ELEKTRİK
9	1/2" Emniyet Valfi	0979	CE	PAKKENS	HİDTEK
10	HEPA FİLTRE	ZGPBL01V	CE	DOMNICKHUNTER	HİDTEK
11	GÜÇ KAYNAGI	MDR100-24	CE	MAINWEL	ENKOSİS
12	SİGORTA	C60	CE	SIEMENS	BEHA ELEKTRİK
13	KONTAKTOR	3TF42	CE	SİEMENS	BEHA ELEKTRİK
14	MOTOR KORUMA ROLESİ	3RV1011-1GA10	CE	SİEMENS	BEHA ELEKTRİK
15	3 MM 316 L PASLANMAZ SAÇ	AISI 316 L	3,1	ER PASLANMAZ	ER PASLANMAZ
16	6 MM 316 L PASLANMAZ SAÇ	AISI 316 L	3,1	ER PASLANMAZ	ER PASLANMAZ
17	10 MM 304 PASLANMAZ SAÇ	AISI 304	3,1	ER PASLANMAZ	ER PASLANMAZ
18	50 MMM 304 PASLANMAZ SAÇ	AISI 304	3,1	ER PASLANMAZ	ER PASLANMAZ
19	2 MM 1/2"PASLANMAZ 304 BORU	AISI 304	3,1	ER PASLANMAZ	ER PASLANMAZ
20	2 MM 1"PASLANMAZ 304 BORU	AISI 304	3,1	ER PASLANMAZ	ER PASLANMAZ
21	3 MM 2" PASLANMAZ 304 BORU	AISI 304	3,1	ER PASLANMAZ	ER PASLANMAZ

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