CERTIFICATE

AT Sertifikası

Tam Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 3

Sertifika Numarası: 1984-MDD-21-738

Aşağıda bahsi geçen kuruluşun tam kalite güvence sistemine ait incelemesinin, tıbbi cihazlara dair 93/42/AT yönetmeliği Ek-II (Bölüm 4 muaf tutularak) gereksinimlerine göre yapıldığını beyan ederiz. Tam kalite güvence sisteminin yukarıda bahsi geçen yönetmeliğin ilgili koşullarına uygunluğunu tasdik ederiz.

Kuruluş:

ERYİĞİT ENDÜSTRİYEL MAKİNE VE TIBBİ CİHAZLAR İMALAT İTHALAT İHRACAT İNŞAAT TİCARET ANONİM ŞİRKETİ

İvedik Organize Sanayi Bölgesi Öz Anadolu Sitesi 1453. Sok. No:3 06370 Ostim, Ankara, Türkiye

Ürünler: Buhar Sterilizatörü, Yıkama ve dezenfeksiyon cihazı, Oksijen Üretim ve Depolama Sistemi, Hidrojen Peroksit Gaz Plazma Sterilizatörü

Ürünler, sertifikanın bir parçası olan ekte tanımlanmış olup, ek bir sayfadan oluşmaktadır. Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Rapor No: M.2927.12
Son Geçerlilik Tarihi: 27 Mayıs 2024

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

12 Şubat 2021, İstanbul, Türkiye

Digitally signed by Jighili Tatiana
Date: 2021.04.16 18:08:21 EEST
Reason: MoldSign Signature
Location: Moldova

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@kiwa.com

CERTIFICATE

AT Sertifika Eki:

Tam Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 3

Sertifika No: 1984-MDD-21-738

İlgili tıbbi cihazlar;

Ürün: Buhar Sterilizatörü

Tipleri	Model Adı
ERS, STR	75, 75V, 4407S, 4407V, 4410V, 4410S, 5510S, 5510V, 5510D, 5512S, 5512V, 5512D, 6610S, 6610V, 6610D, 6613S, 6613V, 6613D, 7712S, 7712V, 7712D, 7715S, 7715V, 7715D, 7717S, 7717V, 7717D, 2000S, 2000V, 2000D
GOLDBERG	75, 75V, 120S, 120V, 160S, 160V, 250S, 250V, 250D, 300S, 300V, 300D, 422S, 422V, 422D, 550S, 550V, 550D, 675S, 675V, 675D, 840S, 840V, 840D, 1000S, 1000V, 1000D, 2000S, 2000V, 2000D

Ürün: Yıkama ve Dezenfeksiyon Cihazı

Tipleri	Model Adı
TEKSTERİL	TSY 150, TSY 225, TSY 290M, TSY 290O, TSY 360, TSY 3000
GOLDBERG	GY 150, GY 225, GY 290M, GY 290O, GY 360, GY 3000

Ürün: Oksijen Üretim ve Depolama Sistemi

Tipleri	Model Adı
GOLDBERG	Oxy-Gold 2, Oxy-Gold 3, Oxy-Gold 4, Oxy-Gold 5, Oxy-Gold 7, Oxy-Gold 11, Oxy-Gold 15, Oxy-Gold 18, Oxy-Gold 22, Oxy-Gold 30, Oxy-Gold 37, Oxy-Gold 45, Oxy-Gold 55, Oxy-Gold 75, Oxy-Gold 90, Oxy-Gold 110, Oxy-Gold 132, Oxy-Gold 160, Oxy-Gold 200, Oxy-Gold 250, Oxy-Gold Poliklinik10, Oxy-Gold Ambulans10, Oxy-Gold M10, Oxy-Gold M20, Oxy-Gold M30, Oxy-Gold M40, Oxy-Gold K4, Oxy-Gold K5, Oxy-Gold K7, Oxy-Gold K11, Oxy-Gold K15, Oxy-Gold K18, Oxy-Gold K22, Oxy-Gold K30, Oxy-Gold K37

Ürün: Hidrojen Peroksit Gaz Plazma Sterilizatörü

Tipleri	Model Adı
TEKSTERİL	TSP 80, TSP 120, TSP 135, TSP 160, TSP 200
GOLDBERG	GP 80, GP 120, GP 135, GP 160, GP 200

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış kuruluş olup kimlik numarası 1984'tür.

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

12 Şubat 2021, İstanbul, Türkiye

Kiwa Belgelendirme Hizmetleri A.Ş.
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CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-21-738

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

ERYİĞİT ENDÜSTRİYEL MAKİNE VE TIBBİ CİHAZLAR İMALAT İTHALAT İHRACAT İNŞAAT TİCARET ANONİM ŞİRKETİ

İvedik Organize Sanayi Bölgesi Öz Anadolu Sitesi 1453. Sok. No:3 06370 Ostim, Ankara, Turkey

Products: Steam Sterilizers, Washer disinfectors, Oxygen Production and Storage Systems, Hydrogen Peroxide Gas Plasma Sterilizer

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.2927.12
Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

12 February 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
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CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-21-738

Concerned medical devices;

Product: Steam sterilizers

Types	Models
ERS, STR	75, 75V, 4407S, 4407V, 4410V, 4410S, 5510S, 5510V, 5510D, 5512S, 5512V, 5512D, 6610S, 6610V, 6610D, 6613S, 6613V, 6613D, 7712S, 7712V, 7712D, 7715S, 7715V, 7715D, 7717S, 7717V, 7717D, 2000S, 2000V, 2000D
GOLDBERG	75, 75V, 120S, 120V, 160S, 160V, 250S, 250V, 250D, 300S, 300V, 300D, 422S, 422V, 422D, 550S, 550V, 550D, 675S, 675V, 675D, 840S, 840V, 840D, 1000S, 1000V, 1000D, 2000S, 2000V, 2000D

Product: Washer disinfectors

Types	Models
TEKSTERİL	TSY 150, TSY 225, TSY 290M, TSY 290O, TSY 360, TSY 3000
GOLDBERG	GY 150, GY 225, GY 290M, GY 290O, GY 360, GY 3000

Product: Oxygen production and storage systems

Types	Models
GOLDBERG	Oxy-Gold 2, Oxy-Gold 3, Oxy-Gold 4, Oxy-Gold 5, Oxy-Gold 7, Oxy-Gold 11, Oxy-Gold 15, Oxy-Gold 18, Oxy-Gold 22, Oxy-Gold 30, Oxy-Gold 37, Oxy-Gold 45, Oxy-Gold 55, Oxy-Gold 75, Oxy-Gold 90, Oxy-Gold 110, Oxy-Gold 132, Oxy-Gold 160, Oxy-Gold 200, Oxy-Gold 250,Oxy-Gold Poliklinik10, Oxy-Gold Ambulans10, Oxy-Gold M10, Oxy-Gold M20, Oxy-Gold M30, Oxy-Gold M40, Oxy-Gold K4, Oxy-Gold K5, Oxy-Gold K7, Oxy-Gold K11, Oxy-Gold K15, Oxy-Gold K18, Oxy-Gold K22, Oxy-Gold K30, Oxy-Gold K37

Product: Hydrogen Peroxide Gas Plasma Sterilizer

Types	Models
TEKSTERİL	TSP 80, TSP 120, TSP 135, TSP 160, TSP 200
GOLDBERG	GP 80, GP 120, GP 135, GP 160, GP 200

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

12 February 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

CERTIFICATE

Quality Management System as per TS EN ISO 9001:2015

In accordance with **BBS Belgelendirme Eğitim ve Gözetim Hizmetleri A.Ş.** procedures, it is hereby certified that

ERYİĞİT TIBBİ CİHAZLAR A.Ş.

Özanadolu San. Sitesi 1453. Sk. No: 3
06378 İvedik OSB – Yenimahalle / ANKARA

Applies a management system in line with the above standard for the following scope

Design, Manufacturing, Sales and Service of Central Sterilization Units and Stream Sterilizers, Hydrogen Peroxide Gas Sterilizers, Laboratory Type Autoclave, Washing and Disinfection Devices, Operating Tables, Oxygen Production and Storage System, Medical Purpose Reverse Osmosis Devices.

Certificate No: 1172-01

Initial Certification 09.02.2021
Valid Until 08.02.2024

Certification Body
at BBS A.Ş.

Ankara, 09.02.2021

This certification was conducted in accordance with BBS A.Ş. auditing and certification procedures and is subject to regular surveillance audits.

Kalite Yönetim Sistemi
TS EN ISO/IEC 17021-1
AB-0021-YS

TÜRKAK BDS NO
YS-43F3-3AFC

The authenticity of this certificate may be verified at www.bbsas.com.tr and tbds.turkak.org.tr.
The authenticity may also be checked with the QR Code above.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Cevizlidere Mah. 1246 Sokak No: 4/20 P.K. 06520 ÇANKAYA / ANKARA
www.bbsas.com.tr

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GOLDBERG
Steam Sterilizer
Operation and Maintanence Manual

OUR QUALITY POLICY

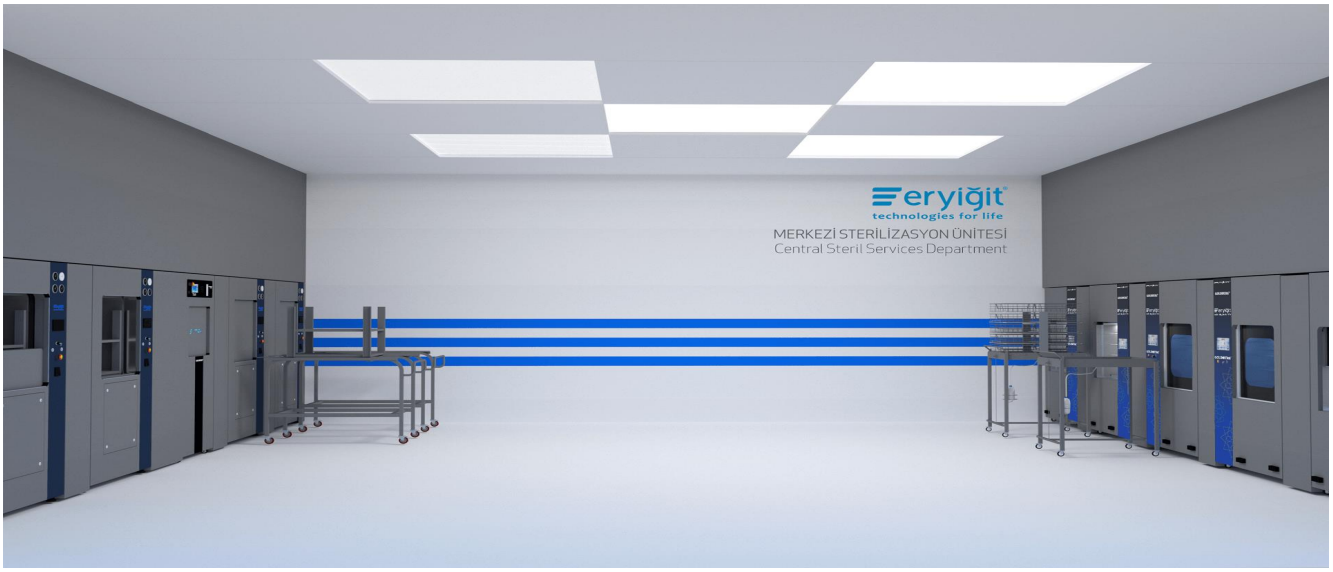
eryiğit®
technologies for life

ISO 9001:2015
EN ISO 14001:2015

ISO 13485

KIWA
CE MARK

0045



Dear Client,

We would like you to have the best efficiency of our product manufactured and tested with extreme care in our modern facilities. Therefore we recommend you to read this manual completely and keep it as a reference booklet.

Please call our service in case of any failure.

Please do not let any person who is not authorized by our company to interfere to the device, in order not to cause more harm to your device which may affect its performance and electrical safety negatively.

CONTACT INFORMATION

HEADQUARTER/ FACTORY

Address :İvedik OSB Özanadolu Sanayi Sitesi 1453 Sokak, No:3 İvedik OSB 06370 Ostim, Yenimahalle / Ankara
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PUBLICATION HISTORY

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Printed in: Ankara

The information contained in this document is subject to change without prior notice.

Warranty

ERYİĞİT provides a two-year guarantee for the device you purchased, starting from the date of delivery.

DECLARATION OF CONFORMITY

Manufacturer's Name: Eryiğit Endüstriyel Makina ve Tıbbi Cihazlar İml. İth. İhr. İnş. Tic A.Ş.

Manufacturer's Address: Özanadolu Sanayi Sitesi 1453 Sokak, No:3 İvedik OSB 06370 Yenimahalle / Ankara

Name of the Product **:** Steam Sterilizer

Model Name:	Goldberg Series	75, 75V, 120S, 120V, 160S, 160V, 250S, 250V, 250D, 300S, 300V, 300D, 422S, 422V, 422D, 550S, 550V, 550D, 675S, 675V, 675D, 840S, 840V, 840D, 1000S, 1000V, 1000D, 2000S, 2000V, 2000D

The Steam Sterilizer (Autoclave) Device is Class II b in accordance with the requirements of Annex - IX Rule 15 under the Medical Device Directive MDD (93/42 / EEC). This product is declared in compliance with the requirements of the 2014/68 / EU Pressure Equipment Directive (PED) and the standards given below.

EMC **:** TS EN 60601-1-2
LVD **:** TS EN 60601-1
Medikal **:** TS EN 285
Pressure Vessel **:** EN 13445-1
EN 13445-2
EN 13445-3
EN 13445-4
EN 13445-5
Validation **:** TS EN ISO 17665-1

EMC Compliance Technical Data

Guidance and manufacturer's declaration-electromagnetic immunity			
Eryiğit Steam Sterilizer is intended for use in the electromagnetic environment as stated below. Eryiğit Steam Sterilizer, its user or customer, must guarantee the use in such an electromagnetic environment.			
IMMUNITY TEST	**IEC 60601-1-2 TEST LEVEL**	**COMPATIBILITY LEVEL**	**ELECTROMAGNETIC CONDITIONS - RECOMMENDATIONS**
Electrostatic Discharge Immunity Test **61000-4-2: 2009**	With ± 8 kV Contact ± 15 kV Airborne	With ± 8 kV Contact ± 815 kV Airborne	Floors can be wood, concrete or ceramic tiles. Floors If the material is synthetic, the relative humidity should be at least 30%.
Immunity Test Against Conducted Distortion Induced by RF Fields **EN 61000-4-6: 2014** **Radiant, Radio Frequency, Electromagnetic Field Immunity Experiment** **EN 61000-4-3: 2006**	Field Strength: 6 V Freakns Range: 150 kHz 80MHz Modulation: AM, 80% Amplitude, 1kHz, Sinusoidal (2 seconds cooldown in 1% steps) 3 V / m (80 MHz 2.7 GHz)	Field Strength: 6 V Freakns Range: 150 kHz 80MHz Modulation: AM, 80% Amplitude, 1kHz, Sinusoidal (2 seconds cooldown in 1% steps) Field Strength: 3 V / m (80 MHz 2.7 GHz) Antenna Distance 1 m Modulation 1 kHz Sine	Eryiğit Steam Sterilizer should only be used in an armored area that has the lowest RF shielding efficiency and has the lowest RF filter attenuation of 31 dB in the frequency range of 150 KHz to 2.2 Ghz for each cable entering the armored area. Field strengths emitted from fixed RF transmitters outside the armored area determined by an electromagnetic zone discovery should be less than 3 V / m. Interference may occur due to proximity to equipment marked with the following symbol: 
NOTE 1 These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. NOTE 2 It is necessary to verify that the actual shielding effectiveness of the armored zone and the strainer attenuation provide the lowest property.			

EXPLANATIONS FOR THE SYMBOLS USED	
SYMBOL	**EXPLANATION**
	**WARNING** **General warning sign**
	**PRESSURE** **Relieve device pressure before service.**
	**USER MANUAL** **Be sure to consult the User Manual prior to service.**
	**VOLTAGE** **Turn off the power and disconnect before service.**

	**IN CASE OF TRANSPORT OR TRANSPORTATION** Use a carrier, carry it safely. Make scheduled migration
	**HOT SURFACE** **Do Not Touch Until It Cools!**
	**It Is Prohibited To Modify The System**
	**Production Date**
SN	**Serial Number**
	**Indicates that the device should not be disposed of with Unprocessed Municipal Waste**
	**Manufacturer**
	**Protective Earth Line**
3N ~	**Three-phase alternating current with neutral conductors**
	**Refers to the Number of the Notified Body 2014/68 PED**
	**Refers to the Notified Body Number 93/42 MD**
	**Strictly Forbidden**
	**Recovery / Recycling**

WHY GOLDBERG SERIES STEAM STERILIZER (AUTOCLAVE)

1. Reliable domestic production,
2. Compliant with TS EN 285 standard, passed the type tests performed by the German accredited organization HYGCEN,
3. Continuously renewed technology and R&D studies,
4. Placing on the market at affordable price ranges,
5. Trained technical personnel, technical service,
6. Easy accessibility, rapid intervention,
7. Economic lifetime, quality material,
8. TUBITAK approved "water and electricity" saving device,
9. 2 years warranty, 10 years spare parts,
10. TS EN 17665-1 Compliance Test by the accredited body HYGCEN VALIDATION,
11. Complete reliability in assembly,
12. Renewed and repeated training process for the user.

WHAT IS STERILIZATION?

When water vapor encounters a cooler object, it concentrates on the material and transfers the energy it carries to this object. It is this energy transmission that provides sterilization. The high energy carried by the pressurized water vapor provides sterilization by transporting it to the objects in time at constant temperature and pressure. Sterilization does not occur unless energy transfer occurs. If there is little air left in the cabin, this energy is transferred to the air and the air is heated. Since air does not have the power to transmit energy, sterilization does not occur in standard periods.

With this method, the death of microorganism cells is caused by protein coagulation and reproduction stops.

After sterilization, steam is exhausted and drying is activated. Drying time can increase in proportion to the material load.

ADVANTAGES OF STEAM STERILIZER DEVICE

- Steam sterilization is the oldest and most used method because it is safe, fast and cost effective.
- It is a suitable sterilization method for all materials except heat sensitive materials.
- It is a sterilization method applicable for materials with long and narrow lumen and closed at one end.
- Does not contain toxic substances harmful to the environment.
- Economic equipment and economic operating cost sterilization method.

STERİLİZASYON TEKNİKLERİ

a) Traditional Sterilization Methods

- Dry heat sterilization
- Steam sterilization
- Ethylene oxide sterilization
- Gamma and electron beam sterilization
- Liquid chemical sterilants

b) Unconventional Sterilization Methods

- Ultraviolet light
- Combined steam and gas plasma
  - ✓ RF plasma - hydrogen peroxide operated
  - ✓ RF plasma - powered by paracetic acid
- Steam sterilizes
- Formaldehyde
- Filtration methods

INTENDED USE and PRODUCT DESCRIPTION

This Device is intended for medical personnel use. It should be used by healthcare personnel and the intended use should not be exceeded.

The Manufacturer Cannot Be Held Responsible For Breaks, Damages And Deteriorations Caused By The Correct Use Of The Device And Not Performing The Necessary Maintenance. Steam Sterilizer Is Designed For Use In Hospital And Laboratories. Sterilization Working Temperature Range Varies Between 121 C and 134 C. Packaged Textile, Surgical etc. Instruments, Rubber Materials and the Relevant Program with Validity in This Range of Temperature Values Can be Selected.

PLC in the System Supervises Each of These Sterilization Processes and Ensures that Necessary Transactions are Made. Thanks to the Printer Used, All Operations Are Recorded For Documentation Process By Instantly Written To The Printer.

In Steam Sterilizers Produced in the Capacities stated below, it can be divided into two groups as Single Door or Double Door. Loading and Unloading of Single Door Steam Sterilizer is done from the door where the control unit is located.

In the Double Door Steam Sterilizer, while the loading is done from the door where the control unit is located, the unloading process is done from the rear door.

1. ISSUES TO BE CONSIDERED

1.1. RECYCLING INFORMATION

- Very valuable raw materials contained in old devices can be recycled for recycling.
- Regarding waste, regulations on waste management should be considered.
- Disconnect old appliances from electricity. Disconnect the mains cable from the device under the supervision of authorized personnel.
- Your new device has been placed in a suitable packaging to avoid any damage during transportation. All materials used for the packaging of the new device are of an environmentally friendly type and can be recycled. Help protect the environment by subjecting the packages to an environmentally friendly disposal and recycling process.
- Do not give the packaging and packaging parts to children for play. Airless mold can suffocate due to foldable cardboard boxes and foils.
- Dispose of the packages as required. All used packaging materials are materials that do not pollute the environment and can be recycled. No chemical treatment has been done on wooden parts.
- Ask your dealer or your municipality about old device disposal methods and waste recycling centers.
- The expected lifetime of the steam sterilizer device, determined according to the PED directive, is 10 years and / or 10,000 cycles.

1.2. SAFETY INFORMATION

- Before operating the device, carefully read the information in the "**Instructions for Use and Assembly**". These instructions contain important information regarding the setup, placement, use and maintenance of the device.
- If you transfer your device to another institution, **give this booklet as a reference.**
- Manufacturer; is not responsible for the consequences of not following the instructions written below.
- Do not operate damaged or disabled devices, if you are not sure, contact your dealer or Authorized Technical Service.
- Connect and install the device according to the assembly instructions. Check that the electrical panel to which the device will be connected and the connection values stated on the type plate are compatible with each other.
- The safety of the electrical connection of the device is only provided if the ground line of the institution is made properly and in accordance with the regulations.
- In case of malfunction, disconnect the device from the electricity during maintenance and cleaning activities. To ensure this correctly, lower the main switch on the grid connection panel, turn off the fuses.
- Repairs to be made on electrical devices should only be carried out by experts.
- Dangers may arise for the person using the device due to incorrect or improper repair work, be careful.
- Do not block or block the drain (Steam-Water) holes of the device.
- Do not allow non-responsible and untrained personnel to do any action with the device.

1.3. WARRANTY CONDITIONS

1.3.1. THE ISSUES COVERED BY THE WARRANTY

A. Product; It is guaranteed against material, workmanship and manufacturing defects for the period defined in the warranty certificate starting from the invoiced delivery date. The dates on the original Warranty Certificate are binding on the parties.

B. The warranty period of the exported devices is 1 (one) year, unless otherwise specified. This period can be extended with special contracts.

C. During the warranty period, maintenance, repair, replacement of parts, etc. by persons not officially authorized by ERYİĞİT TIBBİ CİHAZLAR A.Ş. transactions cannot be made. In case of an intervention and / or detection, the device is out of warranty.

D. Damages and failures that may occur due to interventions other than the authorized service are not covered by the warranty. Labor services within the warranty period are free of charge.

E. Repair time; It starts after the day of written notification to our authorized dealer or our company. The elapsed time will be added to the warranty period.

F. Failure notifications for devices sold into the case of Turkey, the failure to intervene in the following 48 hours, and the device attempts will be made within 10 business days.

G. In case of failure notification for devices sold abroad; If visa applications, climate conditions, transportation conditions and foreign language difficulties are resolved, the device will be activated regardless of time.

H. Detection of defects and needs will be made by technical staff of our company.

İ. The issues regarding the elimination of the fault on site or at authorized services are subject to the approval of the user or the administration.

J. Labor fee is not requested for periodic maintenance defined in the contracts.

K. Consumers will intervene if they notify Eryiğit Medical Devices Inc. in writing of their disputes with Authorized Services that provide maintenance and repair services.

L. The device has a 10-year Maintenance-Repair Warranty for a fee following the end of the warranty period.

M. At the end of the warranty period, a Maintenance-Repair Contract can be made in periods in line with the consumer's request.

N. Administrations; Our company is not responsible for possible risks arising from not using original spare parts after the end of the warranty period.

O. Matters not covered by the warranty are included in the items written in the "User Manual" supplied with the device.

P. This warranty remains in effect if the consumer or consumer institution fulfills its responsibilities to the customer.

Q. Bill of materials must be kept during the warranty period. Materials whose invoices are not submitted are deducted from the guarantee provision.

1.3.2. CONSIDERATIONS NOT COVERED BY WARRANTY FOR STERILIZERS

The external factors listed below are the issues that will affect the healthy operation of the device and are subject to a fee for the elimination of malfunctions within this scope.

A. Damages and failures arising from not using the appropriate electrical connections and voltage defined by the manufacturer for the device.

B. Damage and failures arising from incorrect connection of the electrical installation of the device, leveling and installation and improper assembly.

C. Damages and failures arising from the improper installation of the ground line coming to the device.

D. Damages and failures arising from the failure of the repairs required in the electrical system of the devices to be carried out by authorized services.

E. Damages and malfunctions that may arise when the sterilizer device is operated by persons trained in its use.

F. Damage and malfunctions caused by the closure or clogging of the water inlets and steam outlets of the device.

G. After delivery; Damage and malfunctions resulting from external body, plastic parts and PLC screen scratches and breakages during loading, unloading and transportation, and usage errors are not covered by the warranty.

H. Fire and lightning strikes, voltage drop or surplus; Faulty electrical installation and incorrect connection, use of voltage different from the voltage range written on the product's label are not covered by the warranty.

İ. Damages and malfunctions occurring during the room renovations and repairs in the area where the device is located. Malfunctions caused by the exploding water installation to the device.

J. Damage and malfunctions caused by descaling and softening of the water feeding the device.

K. Damage and malfunctions caused by the temperature and humidity of the environment where the device is used is not within the desired values.

L. Damages and failures caused by the materials loaded into the device being sharp, piercing and scratching.

M. Although M. Hepa filters vary depending on the air pollution of the environment, they should be replaced at least every 3 months. Out of warranty and subject to a fee.

N. Cover gaskets, condensate evacuators; It should be changed in 6-month periods depending on the quality of the water and the wear of the condensate dischargers. Out of warranty and subject to a fee.

O. Solenoid, Pneumatic and Check Valves, Level Electrodes, Heater Resistances, Cover and Core Seals, Cover Seal Spray and Printer Papers are out of warranty and are subject to a fee.

P. Side covers covering the sterilizer are not covered by the warranty and are subject to a fee.

Q. Installation of the software program on the device and carrying its functions to an advanced level is subject to a fee.

R. Damages and malfunctions caused by sudden and lightning strikes, floods and floods, low or excessive voltage and force majeure specified in the law are not covered by the warranty and are subject to a fee.

S. After completion of final acceptance process is not in control of our company inside and outside Turkey loading, unloading and handling of all damage and faults which are covered by the warranty and is free of charge.

T. Operating Voltage of the device: It is 380 V AC, 50 Hz ± 10 V, it cannot be operated with another electrical power. Damages arising from this are subject to a fee.

U. Lime Water: The water feeding the device must comply with the EN 285 standard. Otherwise, the lime resistance in the water will adversely affect the vacuum motor, check valves, solenoid valves, general water piping and other stainless components and prevent the operation. Malfunctions that may arise from such situations are not covered by the warranty and are subject to a fee.

V. Ambient Temperature must be in the range of +5 ° C / +40 ° C.

W. Humidity must be max 85% (no condensation). The malfunctions that may arise in the electrical and electronic parts of the sterilizers are not covered by the warranty and are subject to a fee.

X. According to EN 285, the properties of the water entering the device should be as follows. Otherwise, problems caused by water in the device will not be covered by the warranty.

Y. Out of warranty faults are repaired for a fee. No claims and compensation can be claimed in cases out of warranty.

Properties of water;

Determinant	Feed water
Residue in evaporation	≤ 10 mg/L
Silicate (SiO2)	≤ 1 mg/L
Iron	≤ 0,2 mg/L
Cadmium	≤ 0,005 mg/L
Lead	≤ 0,05 mg/L
Heavy metals other than iron, cadmium, lead	≤ 0,1mg/L
Chloride (Cl ')	≤ 2 mg/L
Phosphate (P2O5)	≤ 0,5 mg/L
Conductivity (at 25 ° C)	≤ 5 µS/cm
pH value (acidity value)	5 ila 7,5
View	Tortusuz temiz renksiz
Asperity (Σ earth alkalin ions)	≤ 0,02 mmol/L

According to EN 285, the steam properties to be autoclaved should be as follows.

Determinant	Condensation
Silikate ($Si0_2$)	≤ 0,1 mg/L
Iron	≤ 0,1 mg/L
Cadmium	≤ 0,005 mg/L
Lead	≤ 0,05 mg/L
Heavy metals other than iron, cadmium, lead	≤ 0,1mg/L
Chloride (Cl ')	≤ 0,1 mg/L
Phosphate (P2O5)	≤ 0,1 mg/L
Conductivity (at 25 ° C)	≤ 3 µS/cm
pH value (acidity value)	5 ila 7
View	Tortusuz temiz renksiz
Asperity (Σ earth alkalin ions)	≤ 0,02 mmol/L

Z. Narrow Outlay: The outlay of the device should be made with a heat-proof metal pipe of at least 1 ” diameter. Malfunctions that may arise from materials used other than the recommended ones are not covered by the warranty and are subject to apayment.

AA. Insufficient Water: Cut or insufficient water delays or stops sterilization and may cause malfunctions. Malfunctions that may occur are not covered by the warranty and are subject to apayment.

The user, "within the warranty period," ERYİĞİT TIBBİ CİHAZLAR A.Ş. If any person or company makes repairs or maintenance, the device will not be covered by the warranty!

Apart from our company, our company will not accept responsibility for any negative situations and dangers that may arise in the device as a result of maintenance and repairs made by another company.

1.3.3. Working Environment Conditions

- For Indoor Use. - Ambient Temperature +5… +40 oC, Pressure 50-106 kPa.
- Maximum Humidity: 85%, - Acceptable rate of change in voltage: ± 10%
- Pollution Rate: Level 2, IK class 6,

1.3.4. Storage / Transport conditions

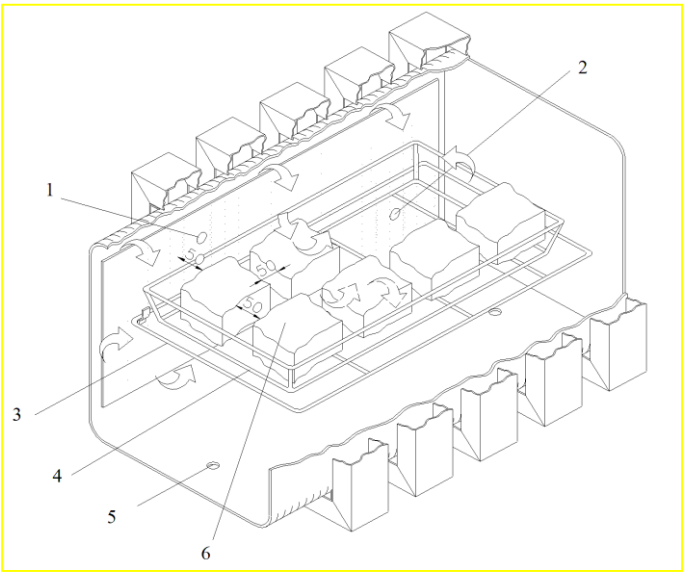
- Storage Indoor - Ambient temperature 0 ° C to + 50 ° C - Pressure +60 kPa to +106 kPa
- Relative humidity 10-90%, non-condensing, - Atmosphere Non-corrosive - Storage time Maximum 1 year

- Birch should be considered when moving the device; The device should always be on its own fixing feet, it should not be placed on another surface in any way, It should be firmly fixed to the transport vehicle, the transport vehicle should be a closed case,

1.4. SAFETY FEATURES

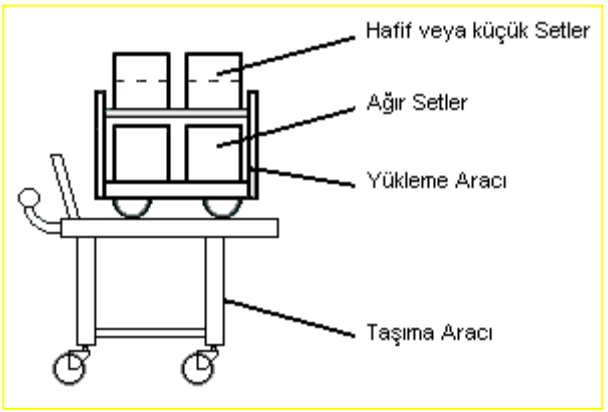
Material Loading Instruction

- Place textiles and large packages on the lower shelf and small packages on the upper shelf.
- Place the paper corresponding to the paper, with the plastic corresponding to the plastic
- Place the packages vertically and the instrument containers on the lower rack in a horizontal position.
- If the instrument containers are to be placed horizontally in the sterilizer, two sets can be placed on top of each other using wire baskets.
- Leave a space between the packages and leave a 5-10 cm space between the wall of the sterilizer
- If the packages are filled into the boiler, the steam turbulence cannot be fully realized. This situation directly affects the sterilization quality.



CORRECT PLACEMENT OF THE LOADING VEHICLE

Heavy loads should be placed on the lower part of the loading vehicle and light loads on the upper part of the vehicle.



1- Front Steam In 2- Rear Steam In 3- Basket Storage Rack
4- Basket 5- Waste Steam Outlet 6- Bundles

The conditions under which the material will be sterilized should be well known by the user. If it is not known, the manufacturer of the material to be sterilized should be consulted.

- Boiler volume should be filled taking into account the STU capacity. STU capacities to be loaded on the devices are specified in item: 3.13. (1 STU = 30X30X60 cm)
- Place the fabric sets so that the hollow ones are side by side and slightly downward.
- Never put heat and moisture sensitive materials, oily substances such as petroleum jelly, liquids, electrical appliances into the sterilizer in order to sterilize them.

1.5. SAFETY SYSTEM FEATURES IN GOLDBERG SERIES STERILIZERS

- The system warns the user when the water runs out. It cuts power / energy when needed.
- The system warns when the cover is open. The program does not start until the door is closed.
- The system warns when there is no steam. The program will not start until steam is supplied.
- The cover cannot be opened before the pressure in the sterilization chamber drops to atmospheric pressure.
- When the electricity network voltage drops, it warns with a sound.
- Warns when the system detects high pressure.
- Pressure detection sensors warn of pressure errors.
- System warns of cable breakages and sensor malfunctions.
- Shows temperature sensing element (PT 100) faults on the screen.
- Autoclave sterilization chamber controlled with 2.8 bar working pressure, 5 bar test pressure.
- In the event of excessive pressure in the autoclave boiler and steam generator, the steam is safely evacuated.
- In cases where the sterilization program does not work, the system; keeps the intracellular pressure under control so that the lid can be opened at any time.
- The system checks the cover gasket of the device with the pressure gauge.
- The system has a cover gasket that ensures tightness until the chamberinner pressure reaches atmospheric pressure.
- System; Do not open the autoclave doors in case of ± 100 mbar pressure difference between the pressure inside the autoclave and atmospheric pressure due to pressure balancing.
- System warning indicators report the difference between internal pressure and atmospheric pressure.
- The system has an emergency door opening button.
- If the temperature of the sterilization room is within acceptable limits, the programs continue. If it is out of these limits, it can be programmed to restart. The printer has the ability to record both situations in time.

1.6. GENERAL SAFETY WARNINGS

WARNINGS: Indicates an event or situation that could result in user injury, death, or other serious adverse reactions in connection with the use or misuse of the device.

WARNINGS: indicates events or situations that may cause any problems in connection with the use or misuse of the device. Such problems may occur in the form of malfunction, malfunction and damage of the device or damage to other items.

INFORMATION: Used for general explanations about the operation of the device.

GENERAL WARNINGS

GOLDBERG Series Steam Sterilizers can be stopped by pressing the emergency stop button in any emergency. In this case, the device discharges the compressed air inside the chamberfor safety.

GOLDBERG Series Steam Sterilizers should be used by trained people and this user should be the only person responsible for the device.

In case the program is canceled or emergency stop is made during the operation of the device; The material loaded on the device to be sterilized must be prepared for the sterilization process and the sterilization must be performed again.

Nothing should be left or stored inside the autoclave when it is not in use. Cover / Covers should be closed.

Sterilized materials are hot, gloves should be worn during autoclave evacuation to avoid user injuries.

The program to sterilize the material to be sterilized should be well known by the user, if not known, the manufacturer of the material to be sterilized should be consulted.

When a new model is produced; The EN 285 standard EK.F aspects are exactly applied to the new model device.

There is a socket inside the device (16 A, 250 V, IP44). It should be used considering that the connection to the socket in the device may have a reduced level of security.

If the bundles are filled into the boiler, the steam turbulence (circulation) cannot be fully realized. This situation directly affects the sterilization quality. While placing the bundles into the device, a space of 5 cm must be left between the boiler wall and the bundles.

Do not operate for more than 8 (eight) hours in a day.

Since the chamberis hot after the run, remove the sterilized materials with gloves.

In case of any liquid spilled into the cell, clean it immediately.

Ionized water should not be used to obtain results in measuring the water level. Water conductivity should be at least 5 µS / cm.

Maximum and minimum supply pressure for steam with maximum flow and usage flow rate min 3 bar / min. should be.

Automatic control device; The details of the sterilization cycle can be printed out as a report at the end of the sterilization cycle, together with the time elapsed for all stages of the sterilization cycle such as pressure, temperature and transition from each stage or sub-stage.

2. SYSTEMS AND FEATURES OF GOLDBERG SERIES STERILIZERS

2.1. DEVICE CONTROL SYSTEMS AND USED PROGRAMS:

- Monitoring of control and sterilization phases on the screen with the help of PLC (Programmable Logistic Controller)
- Managing all sterilization processes with the help of the touch color screen
- Full control with the control unit that has undergone electromagnetic compatibility tests
- Microprocessor controlled main control system

  Programs passed Conformity Tests according to EN 285 product and EN 17665-1 validation standards

USED PROGRAMS

- Bowie-Dick Test Program
- Leak Air Test Program
- 134 ° C Solid Material; / 134 ° C Textile Material
- 121 ° C Rubber Material
- 20 special additional program options are available. Porgram names can be defined by the user.

2.2. STERILIZATION CONTROL SYSTEM:

- Network connection with Ethernet connection (TCP / IP) (optional)
- Connection to central computer system and other computers with RS232 output socket and remote access.
- Access to error information by the user in voice and text
- Opportunities to monitor, change and save the values selected for programming on the graphic display
- Possibility to measure all pressure measurements with electronic pressure transducers without using a pressure switch,
- Continuous control of device security elements with PLC system
- Ability to Monitor Parameters During Sterilization on the Screen
- Which program is used
- Name and step number of the sterilization phase
- Chamberpressure and temperature value
- The time of the sterilization phase and, in case of any error that may occur, the name of the error.

2.3. BOWIE-DICK:

- The color changes on the Bowie-Dick Test paper in line with EN 867-4 Standart and the non homogenous below parameters should be controlled:
- Vacuum pump unfuctionality, air remaining in the device,
- Potential leakage in the autoclave,
- Steam overheated or steam drops,
- Uncondensed gasses,
- Bowie-Dick test, if the hospitals do not have special conditions, should be changed depending on the use frequency. Daily one or weekly one can be changed. Other than this, if there is any doubt on the sterilization, this test can be conducted.

2.4. PRINTER :

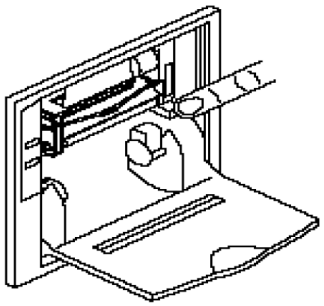
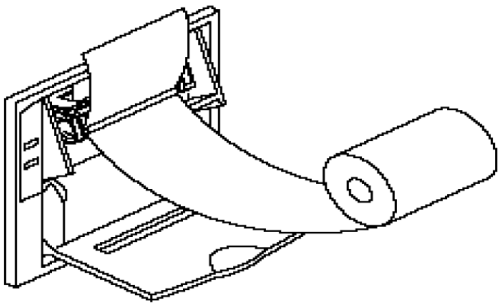
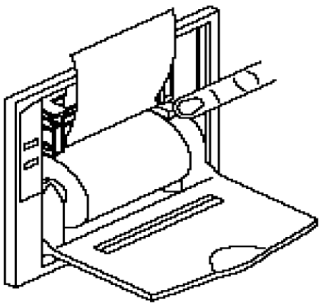
- The following parameters can be monitored with a 40 column alphanumeric printer with thermal technology.
- Date-Time Information
- Sequential Sterilization Number-Program Number
- Pre-Vacuum Time and Stage Number
- Preheat Time and Phase Number
- Sterilization Temperature - Pressure – Time
- Drying Temperature - Pressure – Time

- Error Messages That May Occur in the System
- Total Sterilization Time

NOTE: Because the printout is thermal paper, the information cannot be stored for a long time. For this reason, it will be useful to take a photocopy of the printout and keep it. According to the EN 285 standard, this information must be stored for 10 years for traceability. If our customers want, they can also request a dotmatrix printer on the device. This feature is optional

2.4.1. CHANGING THE PRINTER PAPER

1- Pull the handle of the printer cover until it comes out of the locked position.
2- Remove the remaining paper.
3- Open a few centimeters from the new roll of paper
4- Keep approximately 5 cm of the paper outside of the device as you will be placing a new roll of paper in the chamber.
5- Close the lid by applying even pressure on all sides of the lid until the lid is in the locked position.

2.5. SYSTEM FOLLOW-UP PROGRAM:

- It is optional. "RS232 Output Socket" is available.

2.6. STEAM QUALITY TESTS:

The following parameters can be monitored during the operation of GOLDBERG Sterilizers. These parameters can be monitored depending on the relationship between pressure and temperature.

- Wet Steam
- Saturated Steam
- Superheated steam
- Excessive Heat

Apart from these parameters, air leakage can also be monitored by the device.

2.7. TOUCH SCREEN FEATURES:

- 7 ”Touch Screen 65.000 colors feature
- 256 Pages, RS232, RS422, USB Port and printer port
- Seeing the Process Stages Performed
- Multiple and 20 Program Selection that can be increased if desired
- Possibility to enter multiple and 20 Special Programs, which can be increased if desired
- 16.000 Permanent Memory and Archive Information

2.8. PLC SYSTEM FEATURES:

- 32 Kb Memory
- 16 Input Adjustable Socket Connection
- 16 Outlet Adjustable Socket Connection
- 8 Analog Inputs,
- 24 VDC Supply Socket Connection (Special Power Supply Circuit for protection from voltage changes)
- Real Clock and Time
- Single port RS 232

- Single port RS 485

3. TECHNICAL INFO

3.1. BOILER (CHAMBER) DIMENSIONS

CHAMBER VOLUME	120 Lt	160 Lt	250 Lt	300 Lt	422 Lt	550 Lt	675 Lt	840 Lt	1000 Lt	2000 Lt	75 Lt	75 Lt
MODELS	GOLDBERG 120	GOLDBERG 160	GOLDBERG 250	GOLDBERG 300	GOLDBERG 422	GOLDBERG 550	GOLDBERG 675	GOLDBERG 840	GOLDBERG 1000	GOLDBERG 2000	GOLDBERG 75	GOLDBERG 75V
Diameter (mm)	-	-	-	-	-	-	-	-	-	-	410	410
Height (mm)	520	700	700	700	700	700	700	700	700	1200	-	-
Width (mm)	350	350	350	670	670	670	670	670	670	800	-	-
Depth (mm)	700	700	1050	700	1000	1300	1600	1950	2250	2100	600	600

3.2. DEVICE DIMENSIONS SINGLE SLIDING DOOR

MODELS	GOLDBERG 120	GOLDBERG 160	GOLDBERG 250	GOLDBERG 300	GOLDBERG 422	GOLDBERG 550	GOLDBERG 675	GOLDBERG 840	GOLDBERG 1000	GOLDBERG 2000
Width (mm)	800	800	800	1080	1080	1080	1080	1080	1080	2185
Depth (mm)	1100	1100	1500	1200	1500	1800	2100	2450	2750	2400
Height (mm)	1800	1950	1950	1950	1950	1950	1975	1975	1975	2135

3.3. DEVICE DIMENSIONS DOUBLE SLIDING DOOR

MODELS	GOLDBERG 250	GOLDBERG 300	GOLDBERG 422	GOLDBERG 550	GOLDBERG 675	GOLDBERG 840	GOLDBERG 1000	GOLDBERG 2000
Width (mm)	800	1080	1080	1080	1080	1080	1080	2185
Depth (mm)	1410	1000	1300	1600	1900	2250	2550	2500
Height (mm)	1950	1950	1950	1950	1975	1975	1975	2135

3.4. DEVICE DIMENSIONS SINGLE FLYWHEEL DOOR

MODELS	GOLDBERG 120	GOLDBERG 160	GOLDBERG 250	GOLDBERG 300	GOLDBERG 422	GOLDBERG 550	GOLDBERG 675	GOLDBERG 840	GOLDBERG 1000	GOLDBERG 2000
Width (mm)	800	800	800	1080	1080	1080	1080	1080	1080	2185
Depth (mm)	1130	1130	1530	1230	1530	1830	2130	2480	2780	2430
Height (mm)	1800	1950	1950	1950	1950	1950	1975	1975	1975	2135

3.5. DEVICE DIMENSIONS DOUBLE FLYWHEEL COVER

MODELS	GOLDBERG 250	GOLDBERG 300	GOLDBERG 422	GOLDBERG 550	GOLDBERG 675	GOLDBERG 840	GOLDBERG 1000	GOLDBERG 2000
Width (mm)	800	1080	1080	1080	1080	1080	1080	2185
Depth (mm)	1460	1050	1350	1650	1950	2300	2600	2550
Height (mm)	1950	1950	1950	1950	1975	1975	1975	2135

3.6. DEVICE DIMENSIONS VERTICAL TYPE AUTOCLAVE

MODELS	GOLDBERG 75	GOLDBERG 75V
Width (mm)	890	1050

Depth (mm)	600	620
Height (mm)	1210	1230

3.7. GENERAL TECHNICAL INFO

PAcked medical & surgical instruments	134° C
Textile Materials	134° C
Packed Plastic (Rubber) Materials	121° C
Bowie&Dick Test	134° C
Leak test	S
Additional (optional) Programs	O

O: Optional S: Standard

3.8. VOLUME AND POWER TABLE OF STERILIZER MODELS

MODELS		GOLD BERG 120	GOLD BERG 160	GOLD BERG2 50	GOLD BERG 300	GOLD BERG4 22	GOLD BERG5 50	GOLD BERG6 75	GOLD BERG8 40	GOLD BERG 1000	GOLD BERG 2000	GOLD BERG 75	GOLD BERG 75V
CHAMBER VOLUME (Lt)		120	160	250	300	422	550	675	840	1000	2000	75	75
GENERATOR POWER (3 Phase / 380 ±10 V AC)		20KW	20KW	30KW	30KW	40KW	40KW	50KW	60KW	70KW	90W	13KW	13KW
POWER REQUIREMENT		30KW	30KW	40KW	40KW	50KW	50KW	60KW	70KW	80KW	120KW	20KW	20KW
INSTALLATION VALUES	Main Steam Supply	3/4" Pipe 4-6 Bar	3/4" Pipe 4-6 Bar	1" Pipe 4-6 Bar	1" Pipe 4-6 Bar	1" Pipe 4-6 Bar	1" Pipe 4-6 Bar	1" Pipe 4-6 Bar	1" Pipe 4-6 Bar	1" Pipe 4-6 Bar	1" Pipe 4-6 Bar	1/2" Pipe 3 Bar	1/2" Pipe 5 Bar
		Air: 6-8 bar pressure flow rate, Debi=100 Lt/d. 3/8" Pipe Connection (Sliding Door types)											
	Generator Volume	50 Lt	50 Lt	50 Lt	50 Lt	60 Lt	60 Lt	70 Lt	70 Lt	90 Lt	90 Lt	10 Lt	10 Lt
Water consumption (Lt)		50-60	60-70	70-80	75-85	85-95	95-105	100-110	105-115	115-125	250-300	80-90	80-90

3.9. CHAMBER TEST RESULTS

Generator Water	1/2"Pipe 2-4 Bar 30Lt/h	1/2"Pipe 4 Bar 30 Lt/h
ChamberTest Pressure	5 Bar	
ChamberTest Temperature	150 °C	
ChamberWorking Pressure	2,8 Bar	
ChamberWorking Temperature	140 °C	

3.10. GENERATOR

Generator Water	1/2"Pipe 2-4Bar 40 Lt/h	1/2"Pipe 2-4 Bar 50 Lt/h
Generator Test Pressure	7 Bar	
Generator Test Temperature	160 °C	

Generator Working Pressure	3 Bar
Generator Operating Temperature	143°C

3.11. GENERAL TECHNICAL DATA WEIGHTS

MODELS	GOLD BERG 120	GOLD BERG 160	GOLD BERG 250	GOLD BERG 300	GOLD BERG 422	GOLD BERG 550	GOLD BERG 675	GOLD BERG 840	GOLD BERG 1000	GOLDB ERG 2000	GOLD BERG 75	GOLD BERG 75V
DEVICE (KG)	580	680	750	890	1050	1110	1310	1520	1520	2800	175	190
PACKING (KG)	650	780	900	1070	1250	1310	1510	1720	1920	3200	225	240

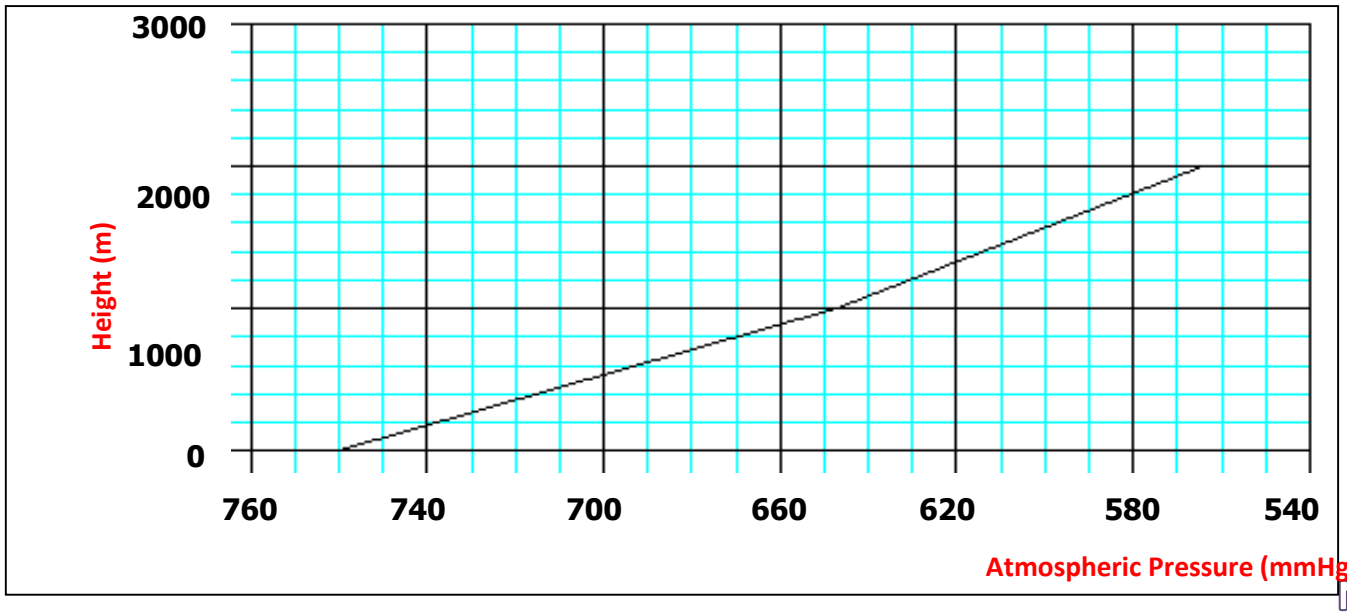
3.12. PRODUCTION AND DOORTYPES ACCORDING TO STERILIZER MODELS

MODELS	GOLD BERG 120	GOLD BERG 160	GOLD BERG 250	GOLD BERG 300	GOLD BERG 422	GOLD BERG 550	GOLD BERG 675	GOLD BERG 840	GOLD BERG 1000	GOLD BERG 2000	GOLD BERG 75	GOLD BERG 75V
CHAMBER VOLUMES DOOR TYPES	120 Lt	160 Lt	250 Lt	300 Lt	422 Lt	550 Lt	675 Lt	840 Lt	1000 Lt	2000 Lt	75 Lt	75 Lt
SINGLE SLIDING DOOR	X	X	X	X	X	X	X	X	X	X		
DOUBLE DOORS			X	X	X	X	X	X	X	X		
SINGLE FLYWHEEL COVER	X	X	X	X	X	X	X	X	X	X	X	X

3.13.CHAMBER MATERIAL SETTING CAPACITY

MODELS	GOLD BERG 120	GOLD BERG 160	GOLD BERG 250	GOLD BERG 300	GOLD BERG 422	GOLD BERG 550	GOLD BERG 675	GOLD BERG 840	GOLD BERG 1000	GOLD BERG 2000	GOLD BERG 75	GOLD BERG 75V
CHAMBER VOLUMES	120 Lt	160 Lt	250 Lt	300 Lt	422 Lt	550 Lt	675 Lt	840 Lt	1000 Lt	2000 Lt	75 Lt	75 Lt
STU CAPACITY	1	2	3	4	6	8	10	12	15	24	-	-

3.14. HEIGHT-PRESSURE CHANGE GRAPH



4. INSTRUCTIONS

4.1. STERILIZER INSTALLATION INSTRUCTIONS (INSTALLATION PRE ARRANGEMENTS)

- The Sterilizer Should Be Installed In An Area That Only Authorized Users Can Reach.
- Do not Install the Sterilizer Near Steam Sources, Where Possible Water Splashes. Water Can Cause Short Circuit and Deterioration of Internal Electronic Circuits.
- Use the sterilizer in a place with good air circulation.
- Do Not Use The Sterilizer Near Heat Sources.
- The area where the sterilizer will be installed and used should be illuminated according to the TS EN 12464-1 Standard.
- Suitable Room Conditions for the device to operate, Temperature Should Be Between 5-40 oC and Maximum Humidity 85% (Without Condensation).

4.1.1. Water System Line And Drainage

a. The water coming into the device must come from the reverse osmosis device.
b. The water asperity must be determined and must be 0.02 mmol / L.
c. Connection should not be made if the user is not sure that the quality of the water is good.
d. In case of using mains water, pressure should not be more than 3 bars.
e. There must be a clipper valve at the water connection point.
f. The water installation should be isolated from the electrical installation.
g. It must be protected in such a way that unauthorized persons cannot interfere with the water line.
h. Metal pipes must be used for the drain.
i. The height of the fastener on the floor of the drain should not exceed 5 cm.
j. The diameter of the pipe to be used in the drain should not be less than 1 ”.
k. There should be no short-distance turnings and narrowing in the drain line.
l. The distance of the outlet of the drain to the main waste manhole should not be less than 1.5 meters.
m. PVC-based material should not be used for drainage.

4.1.2. Electric System Line And Panel

a. The INSTALLED POWER in the place where the device will be installed must be known.
b. The power line coming to the panel should be from a single piece of cable. Spliced cables should not be used. The cable should be 4x10 mm2, 4x16 mm2 or 4x25 mm2 depending on the device model.
c. The ground line coming to the panel should be made by qualified persons in accordance with the standards.
d. All switches and fuses used in the panel must be of high quality.
e. The place where the panel is located should not be close to the plumbing or line.
f. The electricity coming to the panel should provide 3-phase 380 V AC ± 10 Volt power.
g. Fuse should be used depending on the electrical power consumed by the device in the panel.
h. Since our devices are designed and manufactured according to the principles of IEC 60601-2-40, they do not generate critical interference with other devices produced with the same standards.

4.1.3. General Space Requirements:

a. Floors and walls should be suitable for removing accumulated dust and preventing microbial contamination.

b. Ceilings; It should be constructed in a way that minimizes condensation, dust accumulation and possible sources of pollution. It should not allow adhesion and adhesion.

c. Ventilation; It should be ensured that the available air in the room goes out from the clean area to the dirty area or to the outside, with at least 10 air changes per hour.

4.1.4. Ambient Temperature and Humidity

a. CThe ambient temperature where the device will be installed should not exceed the range of +20 ° C to + 30 ° C.

b. A ventilation system should be installed to balance the ambient temperature.

c. While the ambient temperature is absorbed from one line, cold air should be given from the other line.

d. Ambient humidity should be between 30% and 50%.

4.1.5. Compressed Air

a. There should be a drying compressor that will provide compressed air for the devices.

b. The air pressure of the compressor should be in the range of 6-8 bar.

c. The compressed air should also be clean air, free from water and excessive moisture.

d. The connection of the air coming from the compressor with the device should be checked.

4.1.6. Connection

a. Connect the water to the device, if there is any, prevent leakage and check the float.

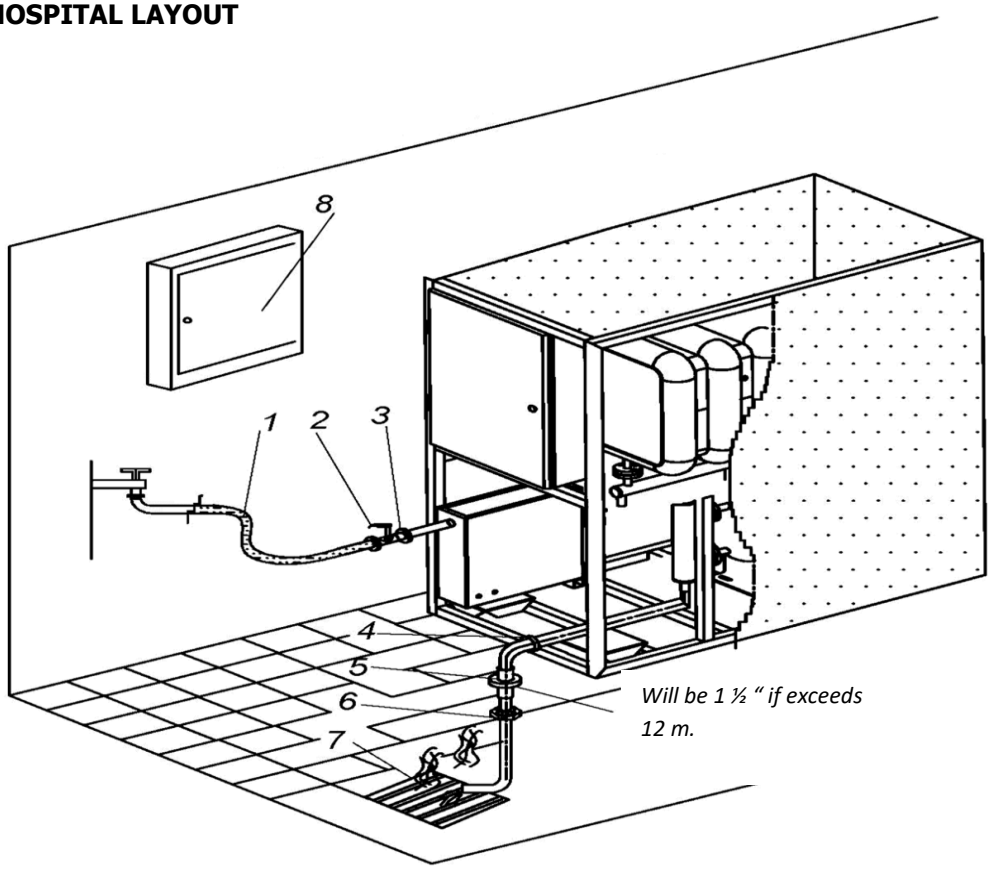
b. Fix the drain and tighten the hose clamps.

c. Firmly connect the cables coming from the electrical panel to the device panel.

d. THE DEVICE IS READY TO RUN.

			Measure	Material	Pressure (bar)	Temperature	Explanation
1	Drainage		At least 2”	Galvanized	5	150	Rigid Pipe Connection
2	Feed water for generator		At least 3/4”	Flexible Plastic Hose	4-8	20-25	Flexible Connection
3	Feed water for cooling		At least 3/4”	Flexible Plastic Hose	4-8	20-25	Flexible Connection
4	Air		Ø8x1mm	Polyamide	5-10	20-25	Flexible Connection
5	Electrical System	25 kW	380V 3P+1N	50 Hz	3*63 A	4x16 10m, 4x25 10-20 m	
		40 kW			3*100 A	4x25 10m, 4x35 10-20 m	
		63 kW			3*120 A	4x25 10m, 4x35 10-20 m	
		80 kW			3*160 A	4x35 10m, 4x50 10-20 m	
	After the plumbing and electrical connections are made, the foot nut is loosened to take the device off the wheels and sit on the feet and the device is taken on the nut.						
	* The cable used in the electrical connection should not be broken or crushed in any way and should be positioned so that it can freely enter the socket.						

HOSPITAL LAYOUT



During transportation, the device must be lifted with the help of a crane and loaded onto the transport vehicle. When the device is placed where it will be placed, it will first stand on fixed feet as shown in the figure. In order to move the device, it must be freed from the fixed feet and brought on wheels. After the device is brought to the installation area, the installation starts with the last electrical connection and after the electrical connection is finished, the device is put into operation. After the installation of the device is completed, before starting the device, the device is placed on its fixed feet again so that the connections are not damaged.

The sterilizer must be installed in an area accessible to authorized users only. Do not install the sterilizer close to steam sources, where there is a possibility of water splash. Water can cause short circuits and malfunction of the internal electronics. Use the sterilizer in an area with good air circulation. Do not use the sterilizer close to heat sources. The area where the sterilizer will be installed and used must be illuminated. Temperature should be between 5-40 oC and humidity 85% (non-condensing) for suitable room conditions for the device to operate.

1. Water supply network line (PPr Pipe ½ "),
2. Globe valve,
3. Water inlet ¾",
4. Drain outlet 1 ¾",
5. Nippel,
6. Sleeve coupling 1",
7. Manhole (waste water drain-heat resistant (160 oC) metal pipe at least 1")
8. Electrical panel

NOTE: The distance from the back and sides of the device should be at least 60 cm, and the distance from the top of the device to the ceiling should be at least 150 cm.

4.2. STERILIZER USAGE INSTRUCTIONS

A. PREPARATION AND CONTROLS;

1. Before using the device, read the "Use and Maintenance Book". Make use of the information in this book in case of any negativity or malfunction. If the problem cannot be solved, inform the authorized person.
2. Check if the inside of the device is empty, clean and the level racks are in place.
3. Check if the electricity, water, drain and air connections of the device are normal.
4. Check whether there is water in the tank of the device. Always keep the water inlet valve open.
5. heck if there is air in the air indicator. (If there is enough air and water in the device, the device will start to heat.)
6. In models with double sliding doors, check whether the clean side cover is closed.
7. Make sure that the cover gaskets are properly placed in their housing.
8. Before starting the device, make sure that the "EMERGENCY STOP" button is not pressed.

B. LOADING;

1. Prepare the material to be sterilized. Load the device with 5-10 cm space left on the chamberedges. Leave 1/3 of the chamberblank. (It is recommended to put the sterilized material into the device with a loading cart and a loading basket.)
2. In case of emergency, press the "EMERGENCY STOP" button.
3. In case of emergency, open the valves on the chamberand generator in order to release the pressure in the device.

C. OPERATION;

1. Turn the key on the front panel of the device.
2. Check that the Emergency Stop Button is On. (Pull the Button Towards You)
3. You saw the main menu appear on the screen.
4. See "No Steam" text on the screen. Other than that, the text "No Water", "No Air" will disappear. If it is not lost, it means there is a malfunction and the device will give an audible warning. Check the water and air.
5. The resistances will be activated and the device will begin to heat. When the generator pressure manometer reaches an average of 3.2 bar (Green Zone), the air manometer reaches an average of 3 bar and the jacket pressure reaches 2.8 bar, the device will be ready and the "No Steam" text will disappear. The device is ready to use.
6. If your device is a Flywheel Cover model, close the cover manually, if it is the model of the Slide Cover, it will close automatically.

D. PROGRAM SELECTION;

1. The device will warn the users and the "READY" lamp will light up.
2. Press the automatic usage button on the screen.
3. Select the program that suits you.
4. Select the program that suits you by moving up and down with the program select arrows.

E. STARTING THE PROGRAM;

1. Start the program by clicking the "START" button in the lower right corner of the screen..
2. Make sure that the cover is closed. The device will start the selected program.

F. STAGES OF THE PROGRAM;

1. Check the phases of the program on the screen. See on the screen that pre-vacuum, pre-heating, sterilization and drying processes are performed sequentially.
2. Observe the stage of sterilization graphically on the screen.
3. If there is a power failure during the sterile phase, a new menu will appear on the device. It will ask whether to continue the sterilization from where it left off. It would be correct to choose "NO" as the suggestion.
4. The program will run automatically according to the values selected by the user. Then, "RECORD MENU" will appear on the screen with a buzzer. The values will be saved by touching the "SAVE" button.
5. Take the printout from the printer and see that the sterilization process has been done successfully. If the sterilization process is not successful, the process is repeated.

G. FINISHING THE PROGRAM;

1. After the device completes its function, the automatic cover will open automatically. The flywheel cover will be opened manually by the user after the end signal of the device. Do not force the appliance door.
2. If the sterilizer is a double sliding cover model, watch that the clean side cover is opened.
3. In double sliding door models, if one of the covers is open, never open the other cover.

H. UNLOADING THE UNIT;

1. Sterilized materials are taken into account by the user.

2. The sterilization process has been successfully completed and your device is ready for a new sterilization.
3. If sterilization will not be done, turn off the device by pressing the "POWER" button.

4.3. STERILIZER CALIBRATION INSTRUCTIONS

TECHNICAL SPECIFICATIONS OF THE SENSORS TO BE USED

1.HEAT SENSOR: THERMOCUPLOR
MEASURING RANGE: 0-200 DEGREES
SENSITIVITY: 0.01 DEGREES

2. PRESSURE SENSOR: DIGITAL MANOMETER
MEASURING RANGE: -0.9- 10 BAR
SENSITIVITY: 0.01 BAR

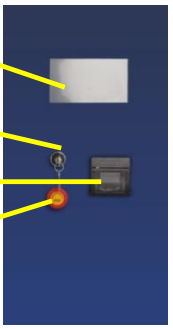
A. TEMPERATURE CALIBRATION

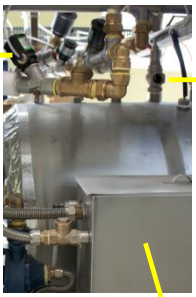
1. Unscrew the coupling fitted for calibration.
2. Connect the calibrated temperature sensor whose specification is specified above.
3. Determine the desired sample reference values at the temperature (121 ° C, 134 ° C).
4. Press the manual control system of the device to 121 ° C button.
5. Wait until the temperature indicator on the device reaches 121 ° C.
6. When the temperature reaches 121 ° C, note the value of the calibrated temperature sensor.
7. Take note of the values of the temperature indicator of the device and the calibrated temperature sensor (connected to the device) every one minute and take a total of 5 values.
8. If the temperature difference is different from the specified standards, change the settings of the temperature sensor on the touch screen.
9. You can do the same operation within 134 ° C.

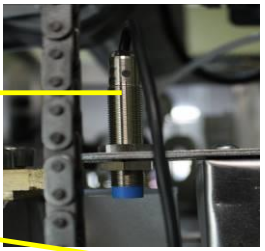
B. PRESSURE CALIBRATION

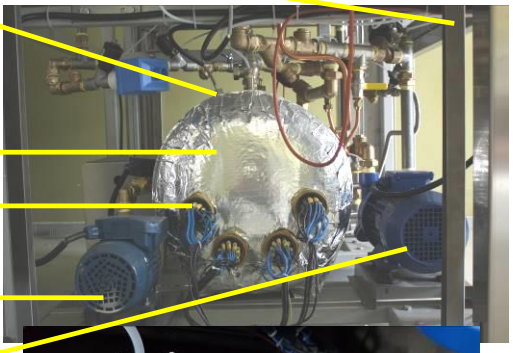
1. Unscrew the coupling fitted for calibration.
2. Connect the calibrated pressure sensor whose specification is specified above.
3. Determine the desired sample reference values at the pressure 70 mbar, 0 bar, 1.2 bar, 2.8 bar)
4. Press the 134 ° C button from the manual control system of the device.
5. Wait until the pressure gauge on the device reaches 2.8 bar.
6. When the pressure is 2.8 bar, note the value of the calibrated pressure sensor.
7. Take a note of the values of the pressure gauge of the device and the calibrated pressure sensor (connected to the device) every one minute and take a total of 5 values.
8. If the pressure difference is different from the specified standards, change the settings of the pressure sensor on the touch screen.
9. For 1.2 bar, 0.0 bar, 70 mbar, press the relevant button on the screen and do the same for other values and degrees.

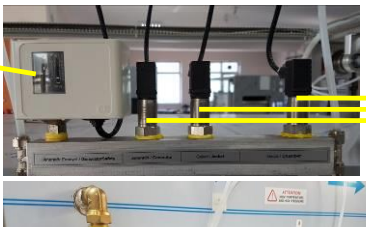
5. SECTIONS AND DESCRIPTIONS OF STERILIZERS

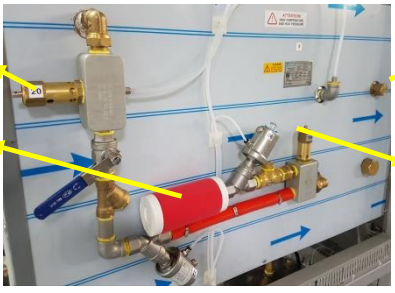


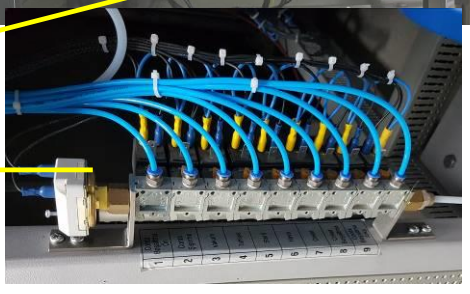












Sequence No	Track name	Part Description
1	Chassis	The carcass that collects all the elements of the sterilizer on it. Side covers on the chassis can be easily removed and installed. Technical intervention to the device is thus facilitated. The device can be moved easily thanks to the wheels attached to the chassis and has height adjustable feet to be fixed to the desired location. It can be manufactured with electrostatic powder paint (oven paint) from AISI 304 quality stainless steel material or carbon steel box profile (40X40mm).
2	Sterilization Room Cell	It is produced in the form of a rectangular prism or a cylinder. It is the volume in which sterilization takes place. It is completely made of AISI 316 L or AISI 316 Ti Quality Stainless Steel. Chambermetal thickness was
3	Steam Shirt Jacket	It provides the heating of the chamberwall by providing steam circulation on the outer surface of the cell. Steam jacket (Jacket) and the cover of the device are made of AISI 304, AISI 316L or AISI 316 Ti Quality Stainless Steel.
4	Steam Generator	It is a separate unit where the steam required for sterilization processes is produced. Working pressure is 3.2 bar manometer pressure. The steam generator produces at least 98% saturated steam. Heat is given to the generator with electrical resistances and the water level is controlled by electrodes. Designed according to the safety calculations of pressure vessels, the steam generator is optionally manufactured from AISI 316L or AISI 316Ti Quality Stainless Steel. The generator has been tested at high pressures and its electrical and mechanical safety has been ensured.
5	Resistance (Heater)	It is used in the production of saturated steam by heating the water in the steam generator. Each of the stainless material is produced as 10 kW.
6	Insulation	Glass wool is used as insulation material in Autoclave Boiler and heat areas. Thanks to the insulation, the maximum temperature that the device can spread to the environment has been tested as 45 ° C (± 3 °
7	Water Level Electrode Box	The boiling of the water in the steam generator causes ripples on the water surface. Fluctuations cause the water level to be measured incorrectly. Therefore, the water level is measured in the water level electrode box directly connected to the steam generator.
8	Water Level Electrodes	Electrodes that measure the lower, upper and safety levels of the water in the steam generator. These electrodes ensure that the water needed by the generator is taken and that the water level does not fall below the resistance level.
9	Air filter	It filters and cleans the air entering the device with the help of HEPA Filters with 0.2 or 0.3 micron pores and 99.99% bacteria filtering feature.
10	ChamberSafety Valve	When the chamberpressure reaches a dangerous value, the safety valve releases the excess pressure.
11	Jacket Safety Valve	When the jacket pressure reaches a dangerous value, the safety valve releases the excess pressure.
12	Pressure Sensors	The sensitivity of the calibrated pressure sensors is 1% at 0.5 bar.
13	Generator Safety Valve	When the generator pressure reaches a dangerous value, the safety valve releases the excess pressure.

14	Manometers	It shows the working pressure values of the device.
15	Water tank	The tank used to meet the water needs of the device (Condensate Tank)
16	PT100 (Temperature Sensor)	It measures the temperature inside the chamberand generator.
17	External Pressure and Temperature Sensor Input	Calibration and validation of the device is the entry prepared for the institutions authorized to do this, to attach their own pressure and temperature sensors to the device.
18	Gasket	It is used for sealing the device's cover system. It is 100% cured silicone based. It is used in covers and flywheel hubs.
19	Cover	It is the part that ensures the safe isolation of the chamberfrom the outside atmosphere. Flywheel Cover or Sliding Cover models can be used optionally. Both cover systems provide sealing of the chamberwith cured heat-resistant silicone gaskets.
20	Emergency Stop Button	It allows the device to stop in any unfavorable situation.
21	Printer	There is a thermal or cartridge ribbon printer on the device. It has automatic winding device.
22	Electric panel	The main place where the electrical equipment is located.
23	Cover Motion Sensor	It allows the cover to work within certain limits.
24	Monitoring Screen	The monitoring screen is touch screen. Provides monitoring of temperature, time, pressure and program phases.
25	Loading Basket	Basket in which the materials to be sterilized are placed.
26	Loading Trolley	It is the car in which the sterilized materials are carried with the loading basket.
27	On Off Switch	It is the key that enables the device to be turned on.
28	Pressure Switch	It prevents the steam generator pressure from rising.
29	Pneumatic Valve	It provides the direction of the steam that will go to the cell.
30	Vacuum Pump	It serves to vacuum inside the chamberand sealing gaskets.
31	Water pump	It serves to flood the generator.
32	Control Valve Coil	It serves to control the air going to the pneumatic valves.

6. STERILIZER STARTING AND USAGE / DISPLAY APPLICATION

Fig.1- MAIN MENU

After our device is turned on from the main power switch, it provides the necessary environment to start sterilization and the image in figure 1 is displayed.

- By touching the menu button, the main menu page in Figure.5 appears.
- By touching the Programs button, the programs page in Figure.6 appears.
- You can open the cover by touching the down arrow button.
- You can close the cover by touching the UP ARROW button.
- For 2000 D and S models the door si open from left to right

When you press the button, the sliding cover of the sterilizer opens and the menu in Figure.2 appears.

Fig.2 - THE DOOR IS OPENING

By pressing the button, the sliding cover of the sterilizer closes and the warning menu in Figure.3 appears.

Fig.3 - THE DOOR IS CLOSING

If there is any problem in the sliding cover, the cover does not work and the warning menu in Figure.4 appears. At this stage, the user starts a study to solve the problem. For this study, the user should review the "Problems and Solutions" section of our User Manual.

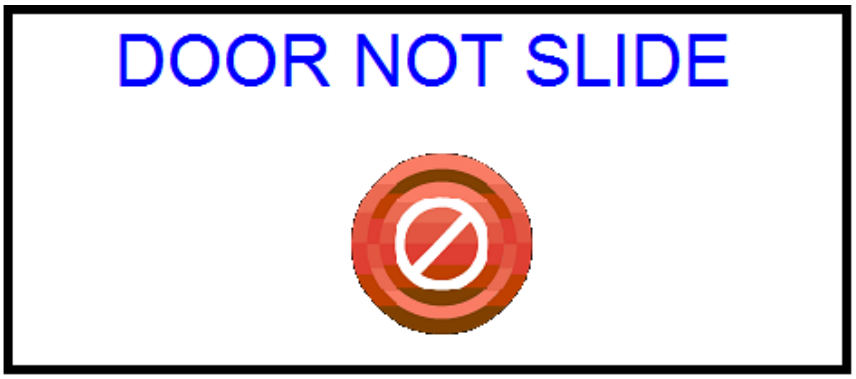


Fig.4 - THE DOOR DOES NOT OPEN

MENU

Fig.5- MENU

One of the buttons seen on the screen in Image;

- Leak Test : The leak test menu is entered. (Fig.5.1)
- Settings : Switches to the settings menü
- Reports : Tracking and transcribing sterilization processes retrospectively performed.
- System : It is the menu where the system operation is monitored visually..
- Program Set : It is the menu that enables the user to make a special program (requires a password and is given to the user by the company).
- Special Programs: It is the menu where special programs prepared by the user are run..

It will be sufficient for the user to press the button to access the previous menü.  . You can switch to the previous menus with the help of this button that you can see in all menus.

When the leak test button in Figure.5 is pressed, the menu in Figure.5.1 will appear on the screen. Leak test is started by pressing the start button.

/

Fig.5.1 - LEAK TEST.1

After the leak test starts, the menu in Fig.5.2 appears.

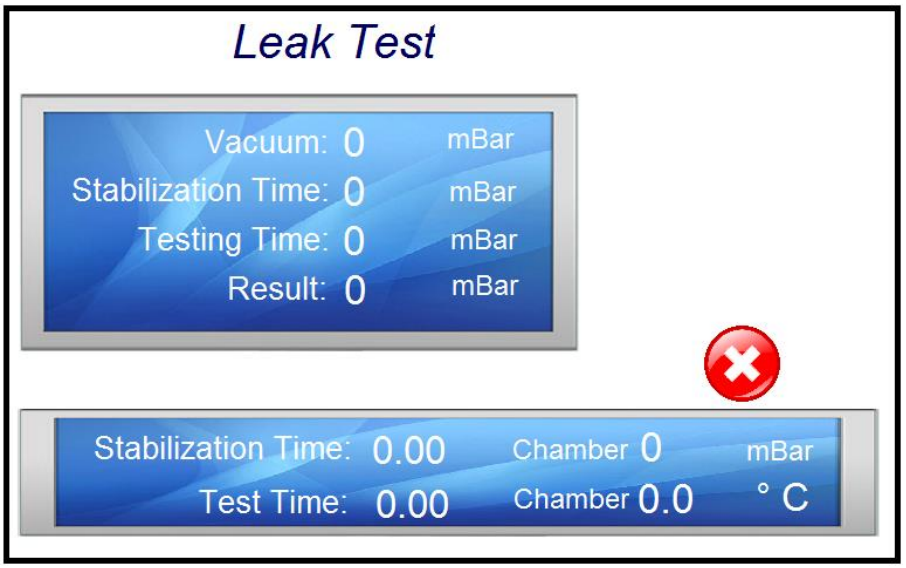


Fig.5.1.A - LEAKAGE TEST. 2

After the test is completed, the result of the test is indicated in the upper right corner of the screen in Fig.5.1.A. When you want to stop at any stage of the test, the test can be stopped by pressing the button.

When the settings button in Figure.5 is pressed, the menu in Figure.5.2 will appear on the screen.

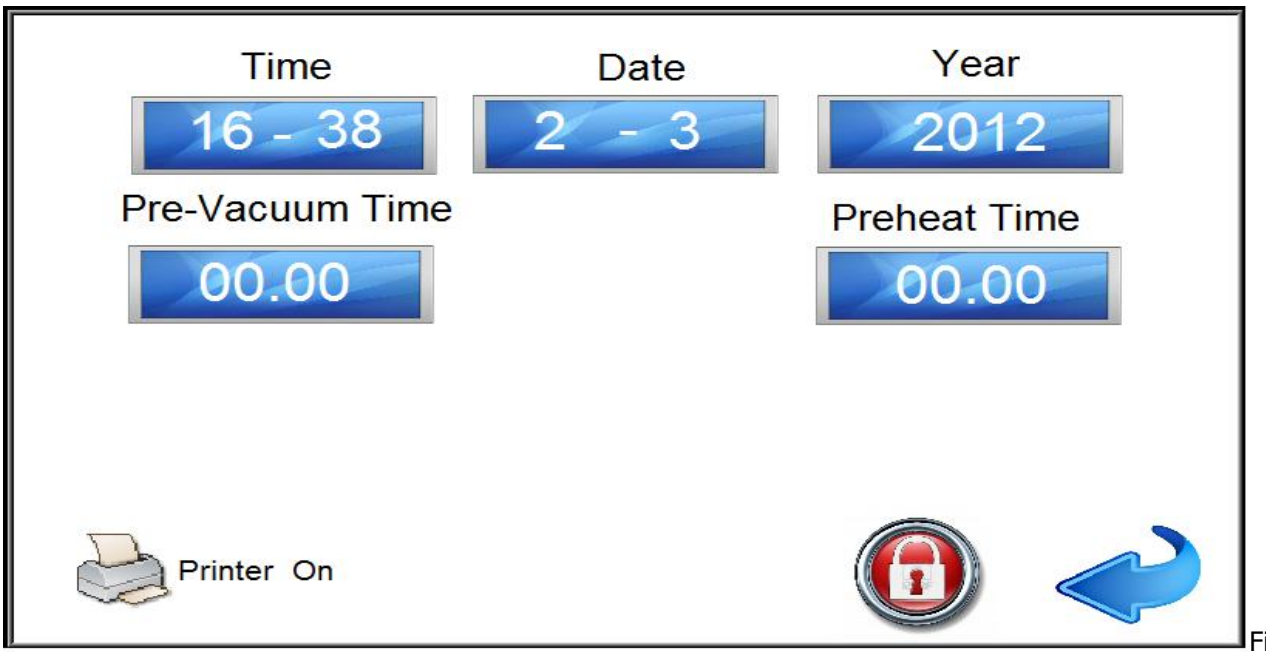


Fig.5.2 - SETTINGS.1

In this menu; date, time, pre-vacuum and preheat times can be set. Besides, the user can also turn the printer on and off. When the user touches the boxes to change the values, a mini keyboard appears on the screen as seen in the menu in Fig.5.2.A and the values are changed in this way. The lock sign seen on the screen has nothing to do with the user. This key is related to technical service.

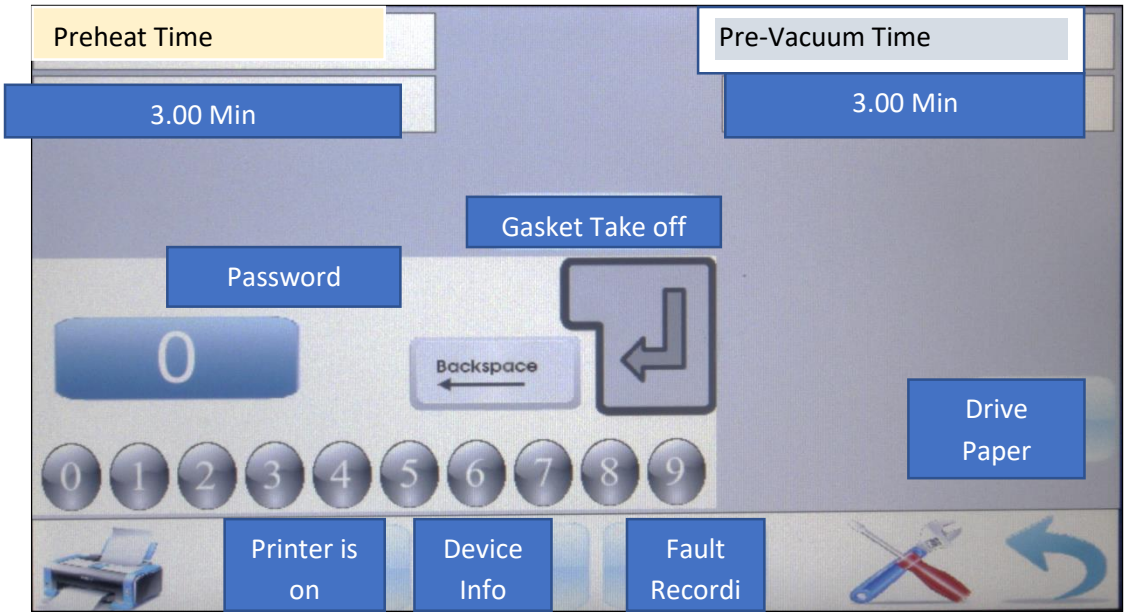


Fig.5.2.A - SETTINGS.2

When the reports button in Figure.5 is pressed, the menu in Figure.5.3 will appear..

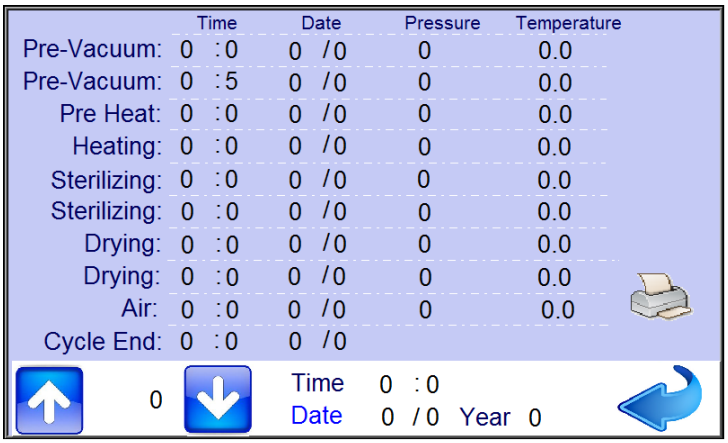


Fig.5.3 - REPORT PAGE

On the report page, you can follow our transactions retrospectively and take the recorded outputs. You can access the archive we are looking for with the arrow keys.

When the system button in Figure.5 is pressed, the menu in Figure.5.4 will appear on the screen. You can visually monitor the operation of the system from this screen.

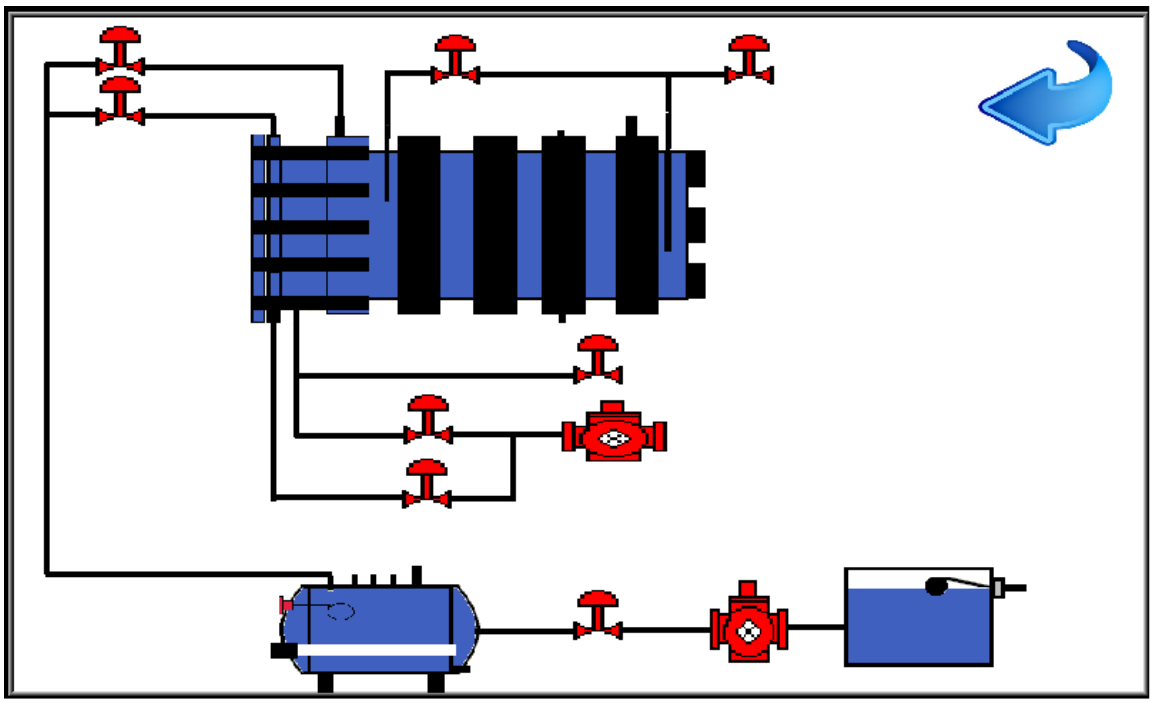


Fig.5.4 - SYSTEM PAGE

When the program set button in Figure.5 is pressed, the menu in Figure.5.5 will appear on the screen.

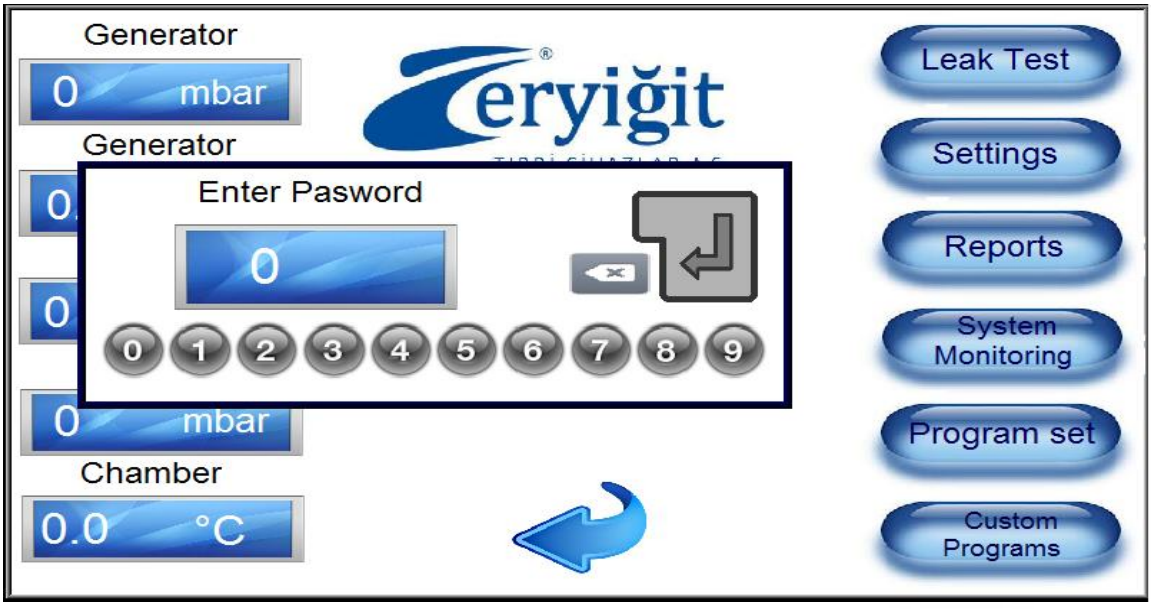


Fig.5.5 - PROGRAM SET PAGE

By entering the password given to her by the company, the user provides the entry of the programs to be made by the user.

When the special programs button in Figure.5 is pressed, the menu in Figure.5.6 will appear.

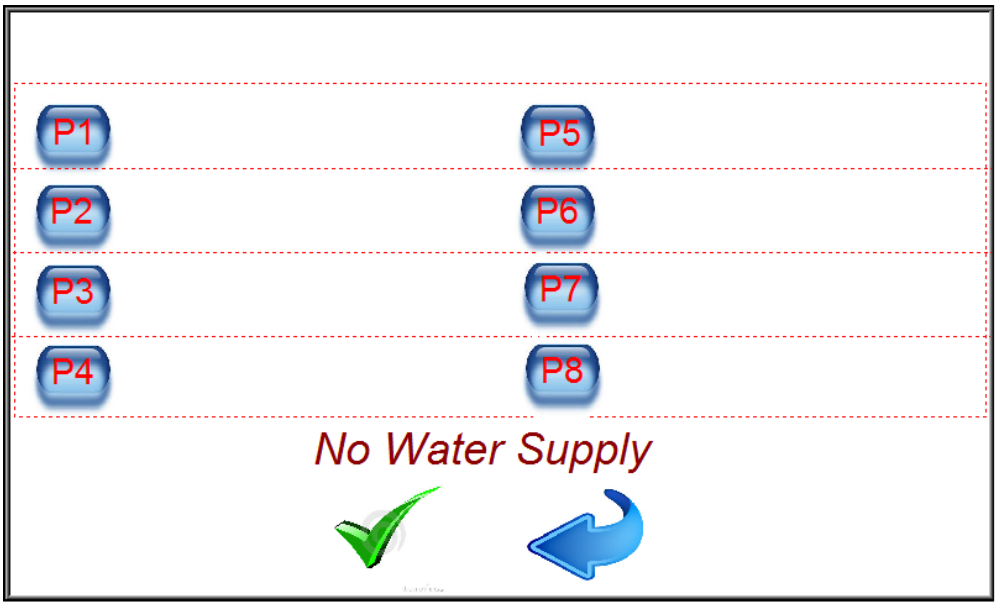


Fig.5.6 - SPECIAL PROGRAMS PAGE

From this menu, you can see the special programs made by the user and run the system by making a selection.

PROGRAMS

Fig. 6- PROGRAMS

From the displayed programs page, start the sterilization process by pressing the button of that program, whichever program we will run. According to this;

P1. Textil,

P2. Surgical Instrument,

P3. Liquid,

P4. Silicon,

P5. Flash,

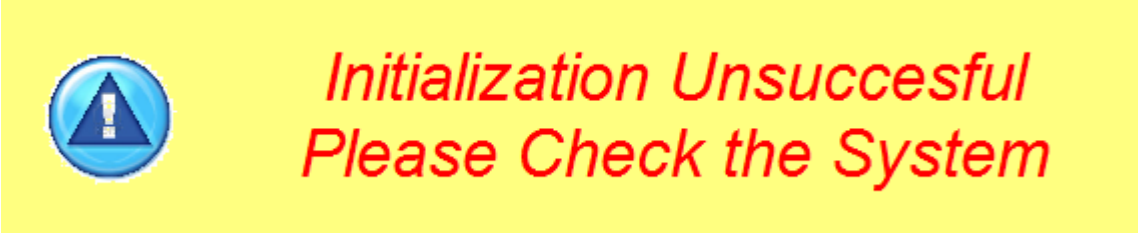
P6. Prion,

P7. Rubber,

P8. Bowie-Dick.

The sterilization process is started by selecting one of the programs.

If there is no problem when the program is started, the sterilization process starts. If there is any problem in the system, the warning message in Figure.7 is displayed.



1 Fig.7- WARNING.1

In about a few seconds, the warning texts in Figure 8 about what the problem is will appear on the screen.

Fig.8 - WARNING.2

At this stage, the user starts a study to solve the problem. For this study, the user should review the "Problems and Solutions" section of our User Manual. When the problem is solved or there is no problem, the screen in figure 9 appears and the sterilization process starts. If the lid of the device is closed while the sterilization process is not active, if it is above or below atmospheric pressure, the menu in Figure 9 is displayed and the system automatically equals the atmospheric pressure.

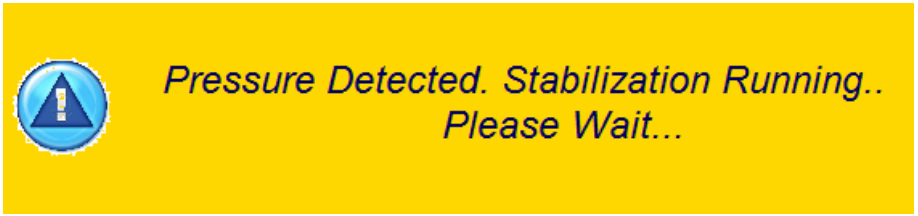


Fig.9 - WARNING.3

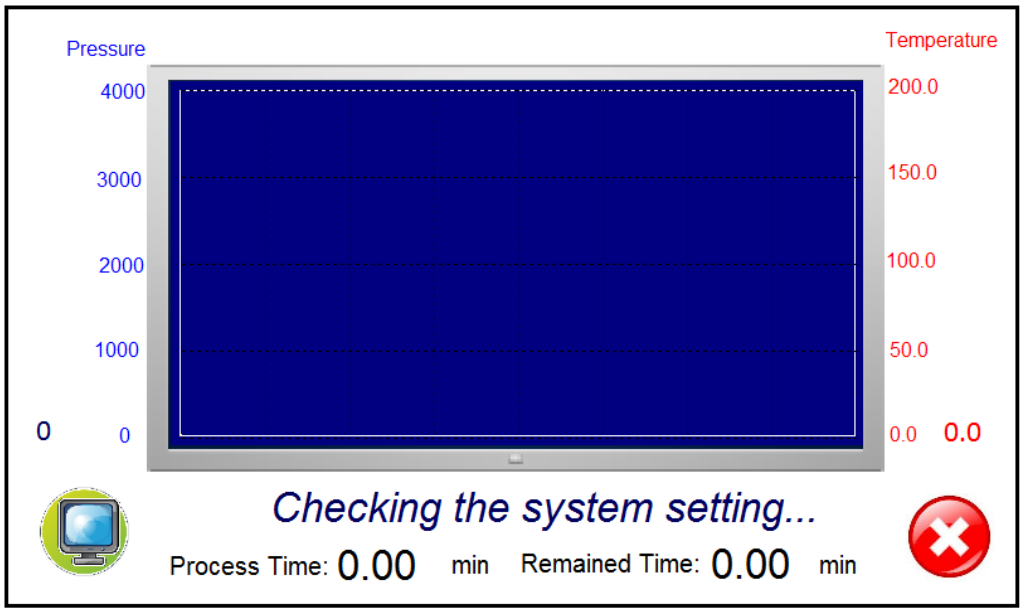


Fig.10 - STERILIZATION PROCESS

By touching the middle of the screen of the device shown in the menu in Figure.10, the menu in figure.11 appears. The temperature and pressure values of the sterilization are instantly checked on this screen. When you touch the same screen again, you will return to the screen you came from.

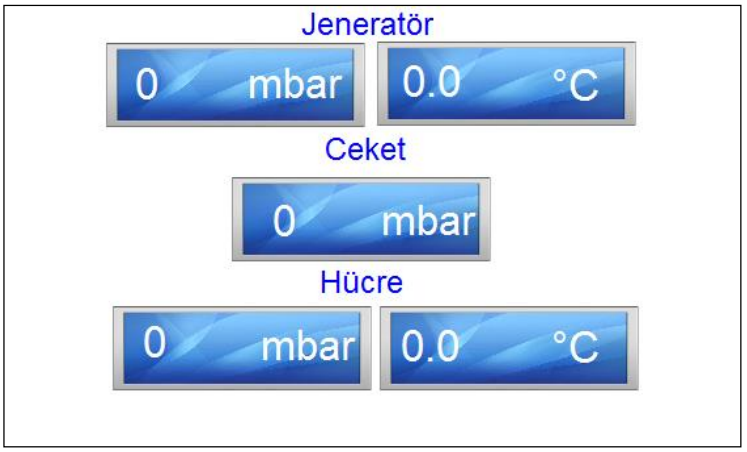


Fig.11 - TEMPERATURE AND PRESSURE INDICATORS

When a problem occurs when the system is running, the menu in Figure.12 is displayed. For the solution of the malfunction, the user should review the "Problems and Solutions" section of our User Manual.

FIG.12 - FAULT PAGE.1

When there is a problem preventing the operation of the device, the menu in Figure.13 appears. When the user sees this warning, he should directly cut the power of the device and call the Technical Service.

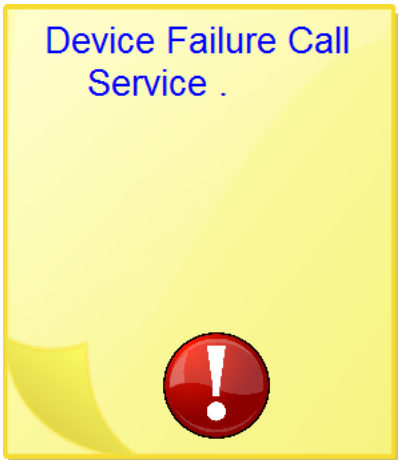


FIG. 13 - FAULT PAGE.2

If there is a power outage during the sterilization process, the menu in Fig.14 appears and the system stops. When the electricity comes on, the warning text in figure.15 is displayed automatically. Accordingly, the user either continues the sterilization process from where it left off or stops the sterilization process.

Fig.14 - ELECTRIC FAILURE WARNING

NOTE: If the system cannot provide the appropriate conditions, the system will not continue the operation even if the user requests.

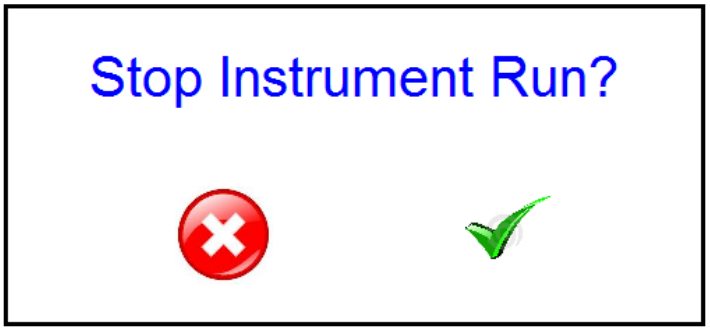


Fig. 15 - WARNING FOR STOPPING STERILIZATION PROCESS

Press the button to stop the system in any emergency during the sterilization process.( ). When you press the button, the menu in fig.15 appears on the screen. To stop the system, press the button to end the sterilization process.

fter the sterilization process is completed, the warning menu in Image.16 appears. By pressing the button, the data of the transaction is recorded. Pressing the button ends the sterilization process.

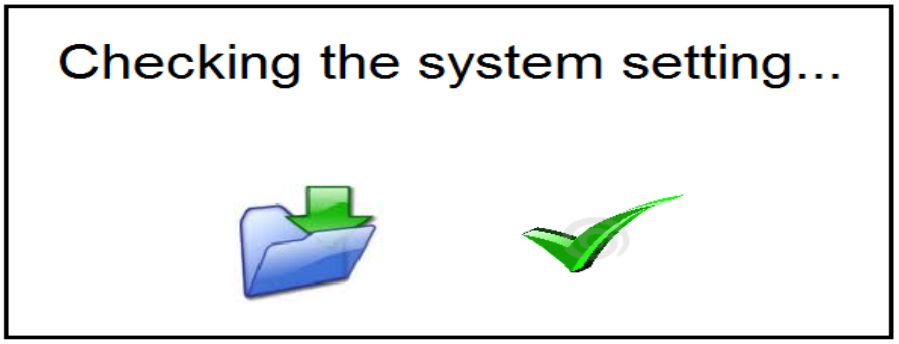


Fig.16 - STERILIZATION PROCEDURE ENDED.

MAINTENANCE

WORK SAFETY FIRST

SECTION 1. SERVICE RELATED ISSUES

1. Cleaning

Cleaning of steam sterilizer devices is done according to the manufacturer's recommendations.

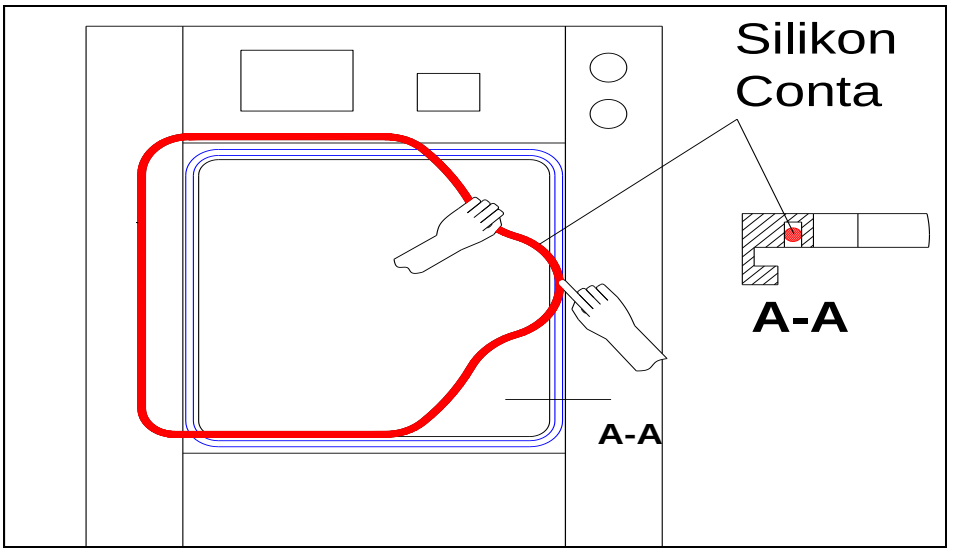
- The inside of the chamber, the rail of the basket, the strainer, the loading cars and the inside of the door are wiped with a soft cloth soaked in warm, detergent and dried.
- he plastic part of the control panel is cleaned without rubbing and with a wet cloth.
- The outer surface of the device is polished by rubbing with the recommended stainless polisher.

2. User Instructions for Sterilizer Maintenance

- Do not disturb and change the stabilization - balance position made by the company during maintenance. Do not change the installation location.
- After the sterilization process is over, unload the sterile materials with the loading cart.
- Check if there are any textile particles that may remain in the cell.
- Once a week, clean the gaskets with the recommended spray.
- Never play with the electrical, electronic and mechanical accessories of the device without the knowledge of the authorized service.
- Do not allow the devices to move during the fine and coarse cleaning of the sterilization center.
- Clean the outer stainless surfaces of the device once a week using the recommended stainless care spray.
- Do not use very hard materials with cutting and scraping properties during maintenance.
- Check the quality of the water and air coming to the device. When you detect an undesirable situation, inform the authorities.
- Drain and renew the water in the generator once a month.
- Disconnect the electricity and water connections of the device that will not be used for a long time.
- Do not allow untrained unauthorized personnel to maintain the device.
- Never put anything inside the device other than materials that will be sterile.
- Do not wipe the inside of the chamberwith chemical compound material.
- During maintenance, do not use petroleum-based, flammable, oily, flammable liquids in line with environmental factors or misdirection.

3. Gasket Replacement

After the gasket change in the sterilizers, it is RECOMMENDED to spray the gasket surfaces at least once a week for maintenance purposes.



Gasket Replacement

4. Resistances

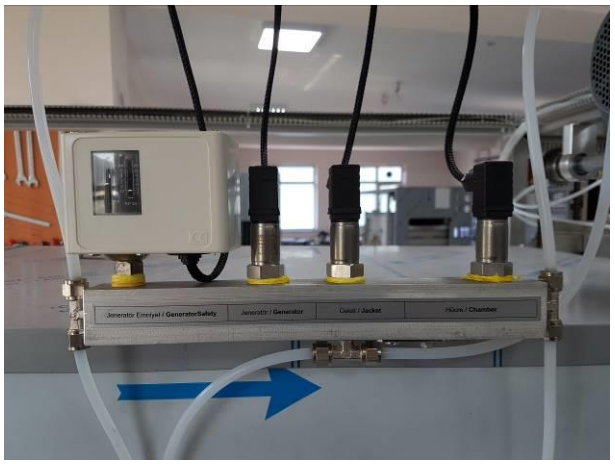
Generator resistances may fail over time due to water lime, as they are exposed to high temperatures.

Therefore;

Resistances must be checked and replaced at least every six months.

It is not recommended to use it by scraping the lime on it.

5. Sensors



(from left to right)

GENERATOR PRESSURE SAFETY SWITCH

CHAMBERPRESSURE TRANSMITTER

GENERATOR PRESSURE TRANSMITTER

JACKET PRESSURE TRANSMITTER

5. Elektrotlar

Calcifications may occur over time due to exposure to high temperatures.

Therefore;

Electrodes must be checked and replaced at least every six months.

The device; There are 3 (Three) electrodes that detect the water level in the generator part.

For this, **if the mains water is calcareous, a "Water Purification Device" must be used with our device.**

Thus, the working life of the device will be extended, a high level of energy saving will be achieved and labor loss will be prevented.

SECTION 2. FAULTS AND SOLUTIONS

a. Steps Before Calling the Service

It may not be necessary to call technical service for every symptom of failure. Before calling technical service, check if you can intervene with the solution suggestions below. Do not intervene or cause any malfunctions related to the software program. Even during the warranty period, you may have to pay all service-related costs in such cases. If the fault cannot be fixed despite the solutions we suggest, call our AUTHORIZED TECHNICAL SERVICE. In this case, do not try any further action yourself, especially do not touch the electrical part.

PROBLEMS AND SOLUTIONS		
FAULT IDENTIFICATION	**CAUSE OF FAILURE**	**TROUBLESHOOTING**
The water level is below the minimum required for resistances to activate. **NO WATER IN THE GENERATOR**	The valve that supplies water to the generator is closed.	Open the valve.
	Faulty water pump and / or valve.	Replace the pump and / or valve..
	SSR is broken.	Change SSR.
	The minimum water level indicator rod is broken.	Replace the water level indicator.
Water level is above the maximum level required for resistances to activate. **OVER PRESSURE AND TEMPERATURE ERROR**	The valve that supplies water to the generator is closed.	Vanayı açınız.
	Faulty water pump and / or valve.	Pompayı ve/veya vanayı değiştiriniz.
	SSR is corrupt.	SSR değiştireniz.
	Maximum water level indicator rod break.	Replace the water level indicator..
	Maximum water level indicator rod break.	Replace the water level indicator.
Insufficient air pressure. **INSUFFICIENT AIR**	Air line valve is closed.	Open the air line valve.
	Insufficient air pressure to the system.	Check the air pressure lines.
Inadequate electricity to the system. **MAINS VOLTAGE ERROR**	Fault in electrical input.	Check the power line.
	Sterilizer fuse blown.	Change fuse.
Excessive pressure rise in the generator. **OVER PRESSURE AND TEMPERATURE ERROR**	Error in pressure reader in generator.	Check the generator pressure gauge. If it is not the same as on the screen, stop the device and inform the authorities.
	Steam valve is out of order.	Replace valve.
The generator pressure safety switch has tripped **OVER PRESSURE AND TEMPERATURE ERROR**	Error in generator pressure reader.	Check the pressure on the manometer. If it is not the same as on the screen, stop the device and inform the authorities.
	Calibration error in pressure safety switch.	Check the pressure on the manometer. If it is not the same as on the screen, stop the device and inform the authorities.
	The valve on the steam pipe from the generator to the jacket is broken.	Replace the valve.
Failure of resistances to be activated in time. **HEATING ERROR**	Error in generator pressure reader.	Check the pressure on the manometer. If it is not the same as on the screen, stop the device and inform the authorities..
	Failure of resistances to perceive commands, operating failure.	Stop the device and inform the authorities.

Resistances work more than their normal working time. **OVER PRESSURE AND TEMPERATURE ERROR**	Error in generator pressure reader.	Check the pressure on the manometer. If it is not the same as on the screen, stop the device and inform the authorities.
	Failure of resistances to perceive commands, operating failure.	Stop the device and inform the authorities.
	Putting a load on the chamberabove its capacity.	Check the load placed on the cell..
The disturbance in the time the steam reaches the desired level in terms of pressure and temperature. **HEATING ERROR**	Error in generator pressure reader.	Check the pressure on the manometer. If it is not the same as on the screen, stop the device and inform the authorities.
	Insufficient steam pressure.	Check the incoming pressure.
	Steam supply valve is broken.	Check whether the steam supply valve is operating correctly.
	Putting a load on the chamberabove its capacity.	Check the load placed on the cell.
Disruption in steam release times. **HEATING ERROR**	The generator steam outlet valve is broken.	Check the generator steam outlet valve.
	Clogged generator exhaust filter.	Check the generator exhaust filter and clean if it is dirty.
	Problem with sterilizer steam output.	Check the chambersteam output.
Generator safety thermostat activates and stops the system. **OVER PRESSURE AND TEMPERATURE ERROR**	Fault in generator safety thermostat.	Check the generator safety thermostat..
	Overheating of the steam inside.	Check the relationship between steam pressure and temperature.
	Electrical failure in the steam generator.	Check the water dipstick.
The loading door does not lock up at the beginning of the sterilization cycle. **DOOR DOES NOT CLOSE**	Piston valve malfunction.	Check the piston valve. In any case, inform the authorized person.
	Seized piston.	Check the piston. In any case, inform the authorized person.
	Piston button broken.	Check the piston knob.
The cover that is emptied at the beginning of the sterilization cycle does not lock. **DOOR DOES NOT CLOSE**	Piston valve malfunction.	Check the piston valve.
	Seized piston	Check the piston.
	Piston button broken.	Check the piston knob.
The loading door does not lock during the starilization cycle. **DOOR DOES NOT CLOSE**	Piston button broken.	Check the piston knob.
Cap not locking the discharged cover during the sterilization cycle. **DOOR DOES NOT CLOSE**	Piston button broken.	Check the piston knob. In any case, inform the authorized person.
The loading door remains locked at the end of the sterilization cycle. **DOOR DOES NOT CLOSE**	Piston valve malfunction.	Check the piston valve. In any case, inform the authorized person.
	Broken air supply valve.	Replace the air supply valve.
	Seized piston	Check the piston. In any case, inform the authorized person.

	Piston button broken.	Check the piston knob. In any case, inform the authorized person.
Door that is emptied at the end of the sterilization cycle remains locked. **DOOR DOES NOT WORK**	Piston valve malfunction.	Check the piston valve. In any case, inform the authorized person.
	Broken air supply valve.	Replace the air supply valve.
	Seized piston.	Check the piston. In any case, inform the authorized person.
	Piston button broken.	Check the piston knob. In any case, inform the authorized person.
At the beginning of the sterilization cycle, the air pressure that should come to the gasket of the lid does not come. **DOOR DOES NOT WORK**	The malfunction in the gasket of the steam inlet valve.	Check the gasket of the steam inlet valve, if there is a problem, replace it.
	ault in the gasket of the steam outlet valve.	Check the gasket of the steam outlet valve, if there is a problem, replace it.
	Door gasket failure.	Check the gasket, if there is a problem, replace it.
Capping with air pressure at the end of the sterilization cycle. **DOOR DOES NOT WORK**	Fault in the gasket of the steam outlet valve.	Check the gasket of the steam outlet valve, if there is a problem, replace it.
	The malfunction in the gasket of the steam inlet valve.	Check the gasket of the steam inlet valve, if there is a problem, replace it.
	Error in calibration seal of pressure switch.	Check the pressure button. If there is a problem, inform the authorized person.
The cap is not tight enough during the sterilization cycle. **DOOR DOES NOT WORK**	Error in the gasket of the steam inlet valve.	Check the gasket of the steam inlet valve, if there is a problem, replace it.
	The fault in the gasket of the steam outlet valve.	Check the gasket of the steam outlet valve, if there is a problem, replace it.
	The cover gasket is defective.	Replace the gasket.
	Error in calibration seal of pressure switch.	Check the pressure button. If there is a problem, inform the authorized person.
Opening the loading door during the sterilization cycle. **DOOR DOES NOT WORK**	The button that closes the tailgate is defective.	Check the button. If there is a problem, inform the authorized person.
Opening the discharge cover during the sterilization cycle. **DOOR DOES NOT WORK**	The button that closes the tailgate is out of order.	Check the button. If there is a problem, inform the authorized person.
Failure to reach the desired pre-vacuum value. **VACUUM ERROR**	Vacuum pump malfunction.	Check the vacuum pump.
	Chambersteam outlet valve failure.	Check the chambersteam outlet valve, if there is a problem, replace it.
	Sterilizer steam output failure.	Check the sterilizer steam outlet valve.
	Failure of the seal in the liquid pump valve.	Check the gasket on the liquid pump valve.
	Clogged chamberfilter.	Clean the chamberfilter leyiniz.
	Error in chamberpressure reader.	Check the chamberpressure on the manometer. If it is not the same as the value on the screen, inform the authorities.
	Chambergasket failure.	Repeat the vacuum test.
The pressure in the chamberis not released in the desired time. **EVACUATION ERROR**	The drain valve is malfunctioning	Replace valve.
	Problematic expense	Check the drain, clear the blocked place.

Failure of the values in the vacuum test to reach the desired values. **VACUUM ERROR**	Vacuum pump malfunction.	Check the vacuum pump.
	Chambersteam outlet valve failure.	Check the chambersteam outlet valve, replace it if there is a problem.
	Sterilizer steam output failure.	Check the sterilizer steam outlet valve.
	Failure of the seal in the liquid pump valve.	Check the gasket on the liquid pump valve.
	Clogged chamberfilter.	Clean the chamberfilter.
	Error in chamberpressure reader.	Check the chamberpressure on the manometer. If it is not the same as the value on the screen, inform the authorities.
	Chambergasket failure.	Repeat the vacuum test.
Failure to reach the desired vacuum level in the drying process. **VACUUM ERROR**	Vacuum pump malfunction.	Check the vacuum pump.
	Chambersteam outlet valve failure.	Check the chambersteam outlet valve, replace it if there is a problem.
	Sterilizer steam output failure.	Check the sterilizer steam outlet valve.
	Failure of the seal in the liquid pump valve.	Check the gasket on the liquid pump valve.
	Clogged chamberfilter.	Clean the chamberfilter.
	Error in chamberpressure reader.	Check the chamberpressure on the manometer. If it is not the same as the value on the screen, inform the authorities.
	Chambergasket failure.	Repeat the vacuum test.
Inability to reach sterilization pressure. **HEATING ERROR**	The malfunction in the steam valve going to the cell.	Check the steam valve in the cell, replace it if there is a problem.
	Error in chamberpressure reader	Check the chamberpressure on the manometer. If it is not the same as the value on the screen, inform the authorities..
	Loading above the capacity of the cell.	Check the loading and do not load above the loading capacity.
No water in the device tank **NO MAINS WATER**	The tank is not at a sufficient level of water	Check the mains water.
Stop closing the door **DOOR SAFETY SWITCH ERROR**	Clamping an object on the door during the door closing phase	Remove the jammed object

SOFTWARE FAULTS SOLUTION PROPOSALS

"PLC Error" Lamp Lighting on PLC	Analog Input Currents Over The Limits	Check the Analog Module
		Check the Sensors
"PLC No Response" on the screen	PLC Communication Error	Check Communication Protocol
		Check Communication Connection and Cables
Printer Error	Printer Does Not Print	Check Communication Protocol
		Check Communication Cables
		Check Printer Feeds,
The device must be restarted after the checks are made for software errors..		

When you call the service, please provide the "Serial Number and Model" of the device. You can find these numbers on the rating plate of the device.

Position the Device Correctly

The installed area where our device will be used should be between "Ambient Temperature Range + 20 ° C to + 30 ° C, Humidity 30% to 50%". Our device should be installed in a well-ventilated place, it should not be exposed to direct sunlight and should be installed in a place away from heat sources (heating, etc.).

Use a Water Purification Device

The device should definitely be used together with the "Water Purification Device" in areas with high water lime ratios. This issue is of great importance in terms of energy saving.

Check Cover Gasket

Keep the lid gasket clean in order to avoid hot air and steam loss. Cover gaskets, which are not cleaned and maintained regularly, are deformed very quickly and cause heat and steam leakage. In this case, the device works continuously and causes energy loss.

Do not overload the device

A good steam circulation is required for the sterilization processes to be healthy and to obtain definite results. If you fill the device chambertoo much, it causes the air circulation to deteriorate, the materials to come out wet and humid, and the generator to be forced.

SECTION 3. PERIODIC MAINTENANCE

In order to use your device more efficiently and for a long time, you should have your periodic maintenance done without interruption.

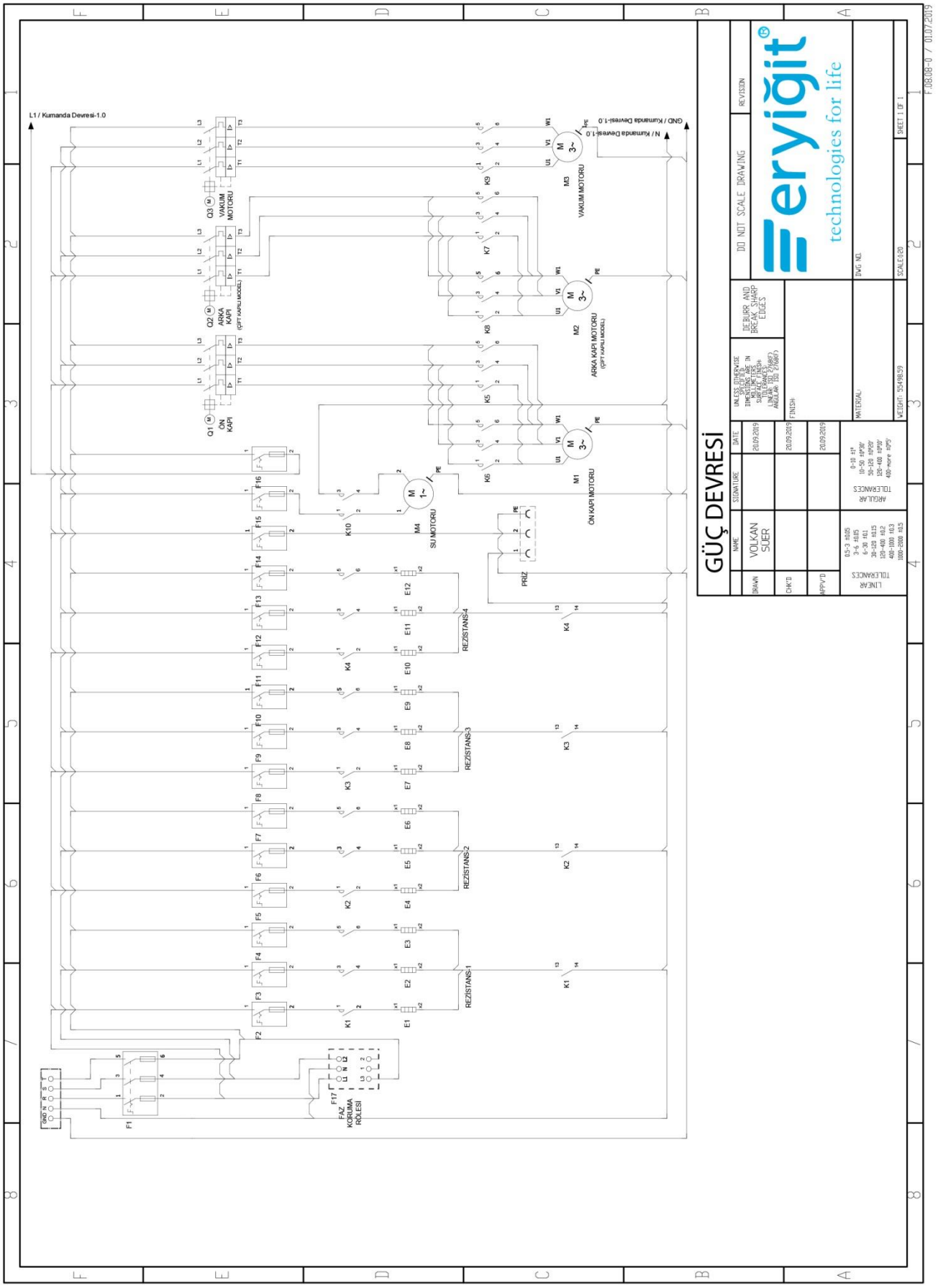
Have your devices have periodic maintenance at least every six months according to your frequency of use.

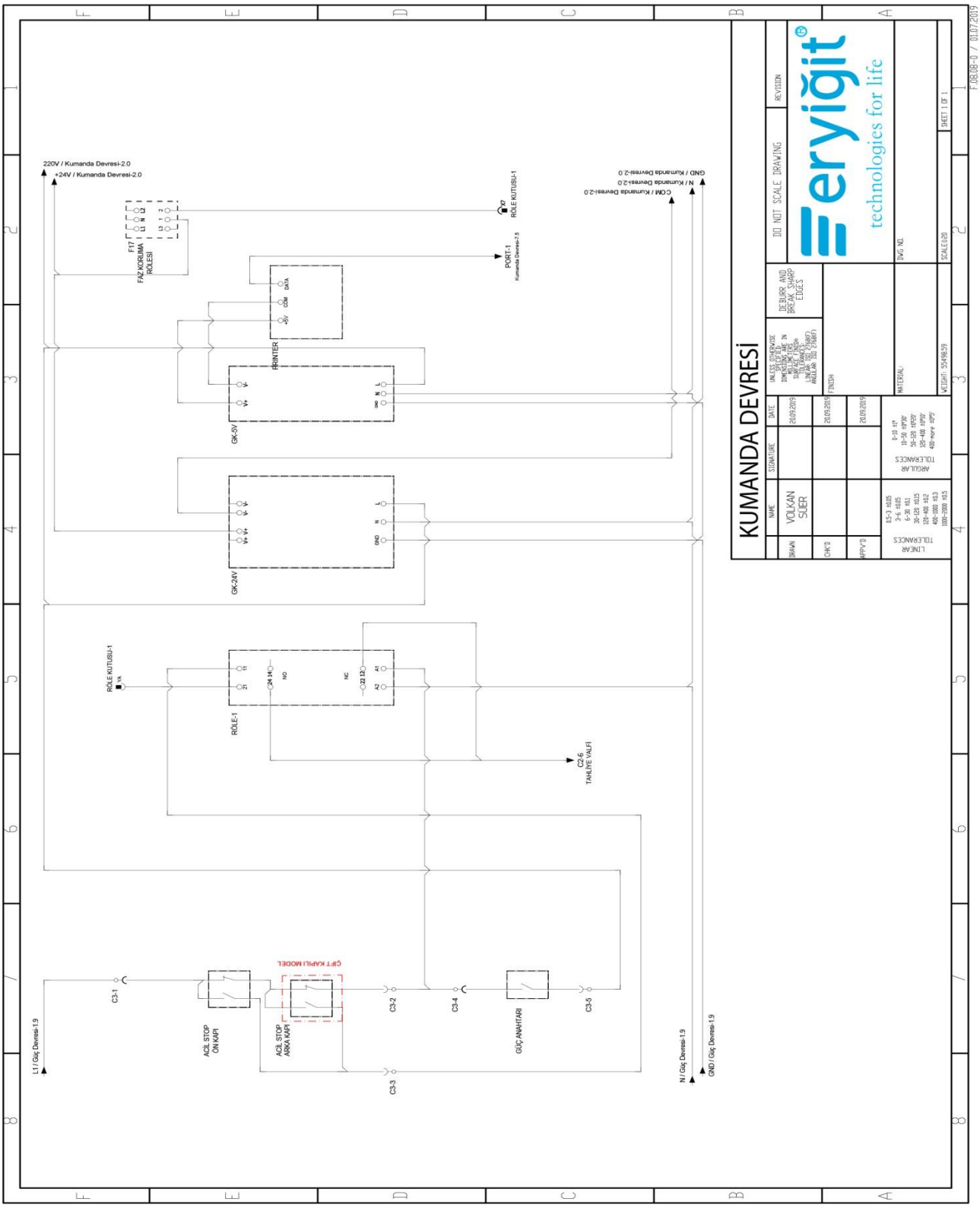
1. HEPA filters should be replaced in 6-month periods depending on the air pollution of the environment.
2. Electrodes must be checked at least every six months and replaced if necessary.
3. The resistances must be checked at least every six months, and replaced if necessary.
4. Hub seals should be checked at least every six months, if necessary, should be replaced.
5. Check valves must be checked at least every six months and replaced if necessary.

Maintenance spray should be applied to the door seals at least once a week.

The device should be cleaned every morning before using it, without using any chemicals.

SSECTION 4. DEVICE CIRCUIT SCHEMES

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RÖLE KUTUSU-1
PORT-1
PRINTER
GK-5V
GK-24V
RÖLE-1
C2-6
TAHLİYE VALFİ
ÇİFT KAPLI MODEL
C3-1
C3-2
C3-3
C3-4
C3-5
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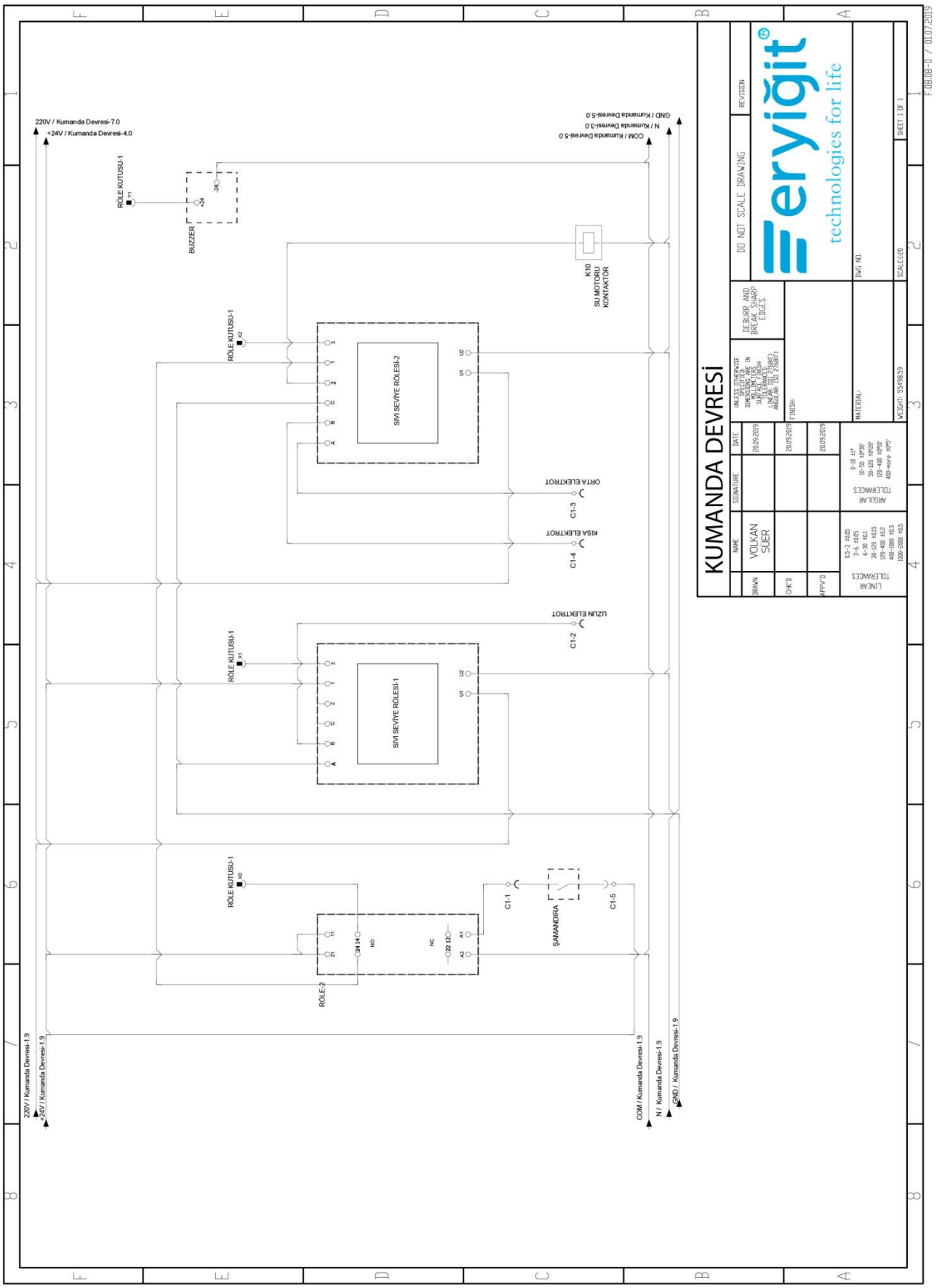
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BUZZER
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SU MOTORU
KONTAKTÖR
SIVI SEVİYE RÖLESİ-2
SIVI SEVİYE RÖLESİ-1
ORTA ELEKTROT
KISA ELEKTROT
UZUN ELEKTROT
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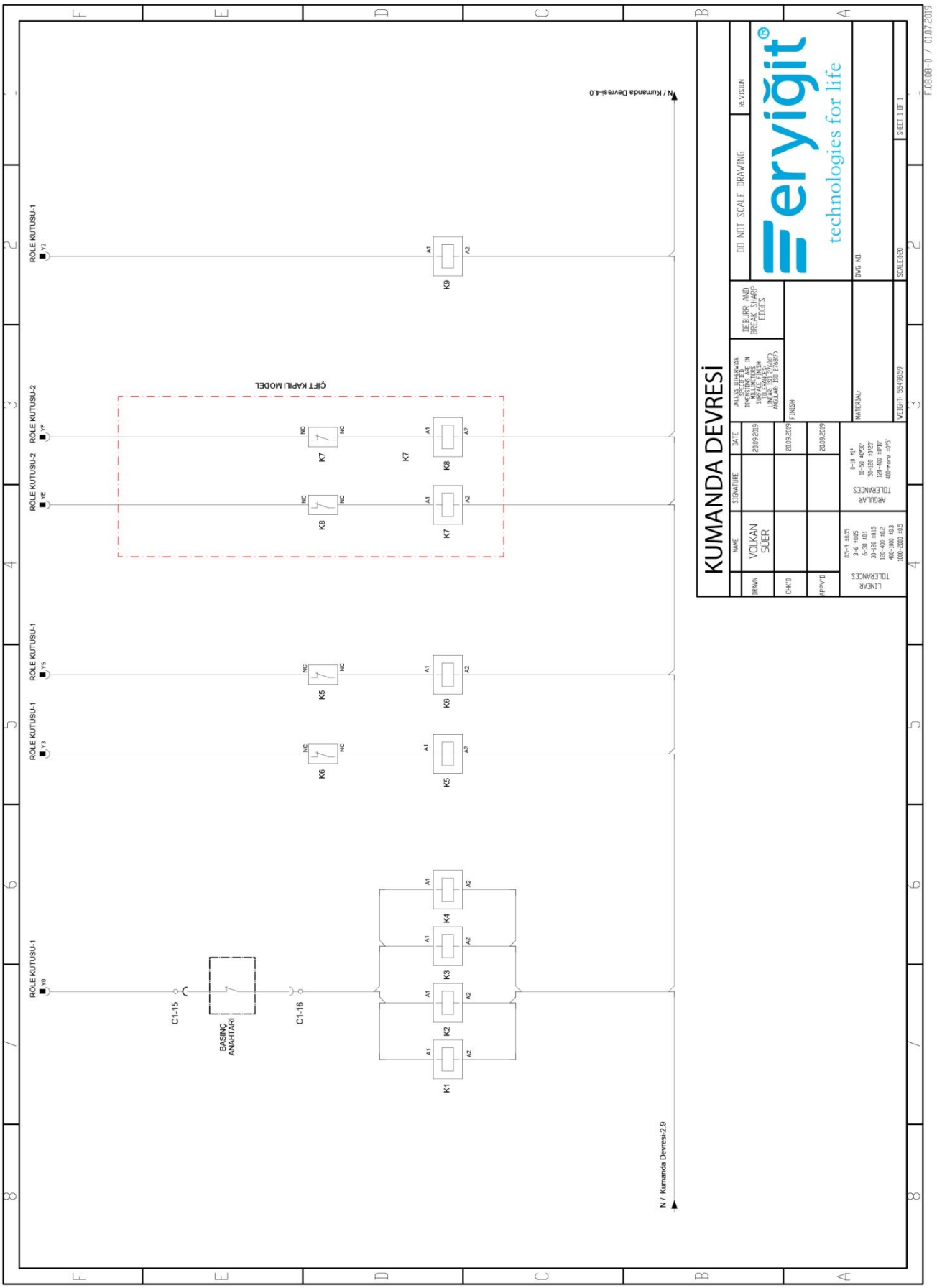
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K8
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C1-16
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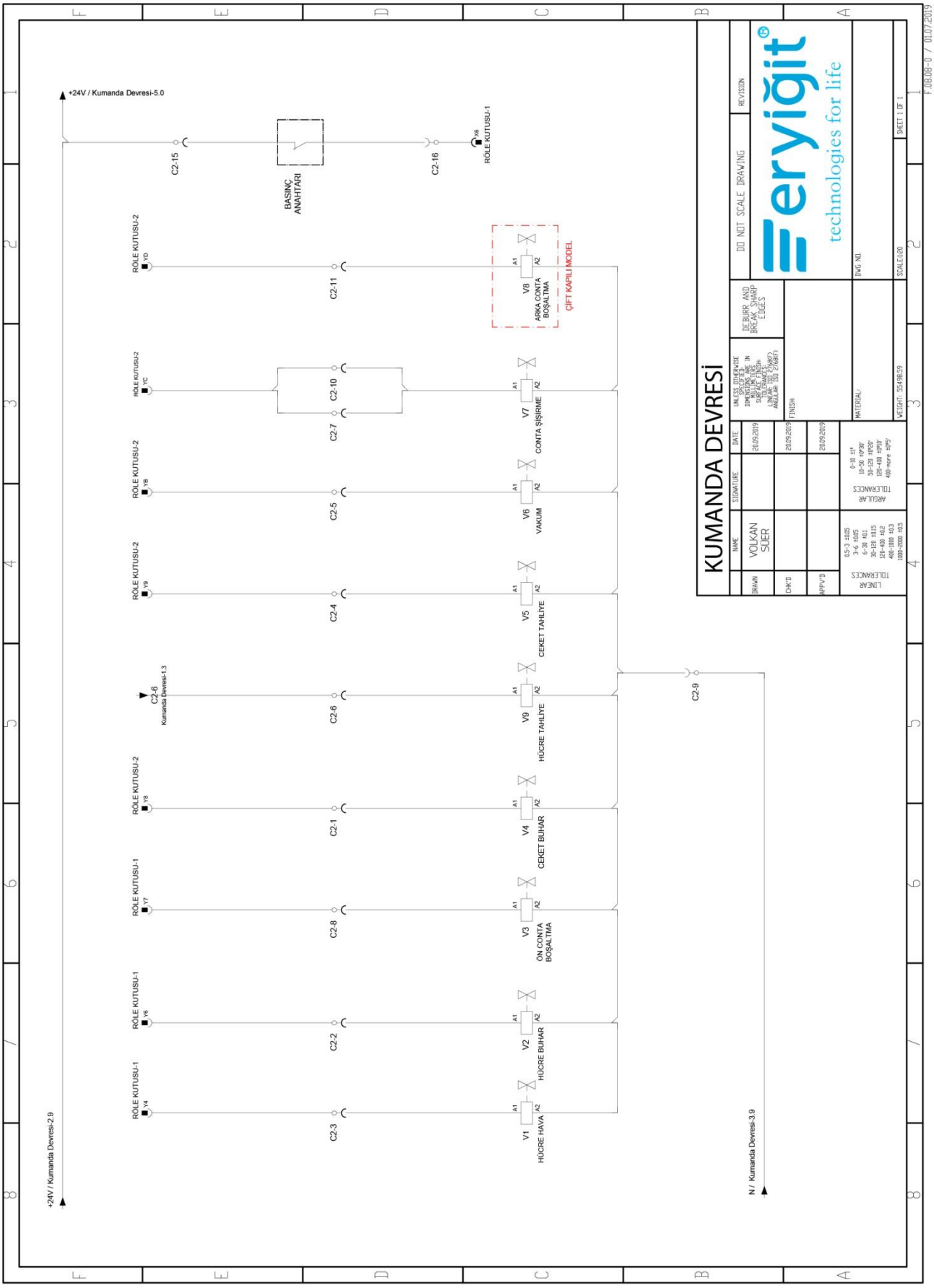
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ÖN CONTA BOŞALTMA
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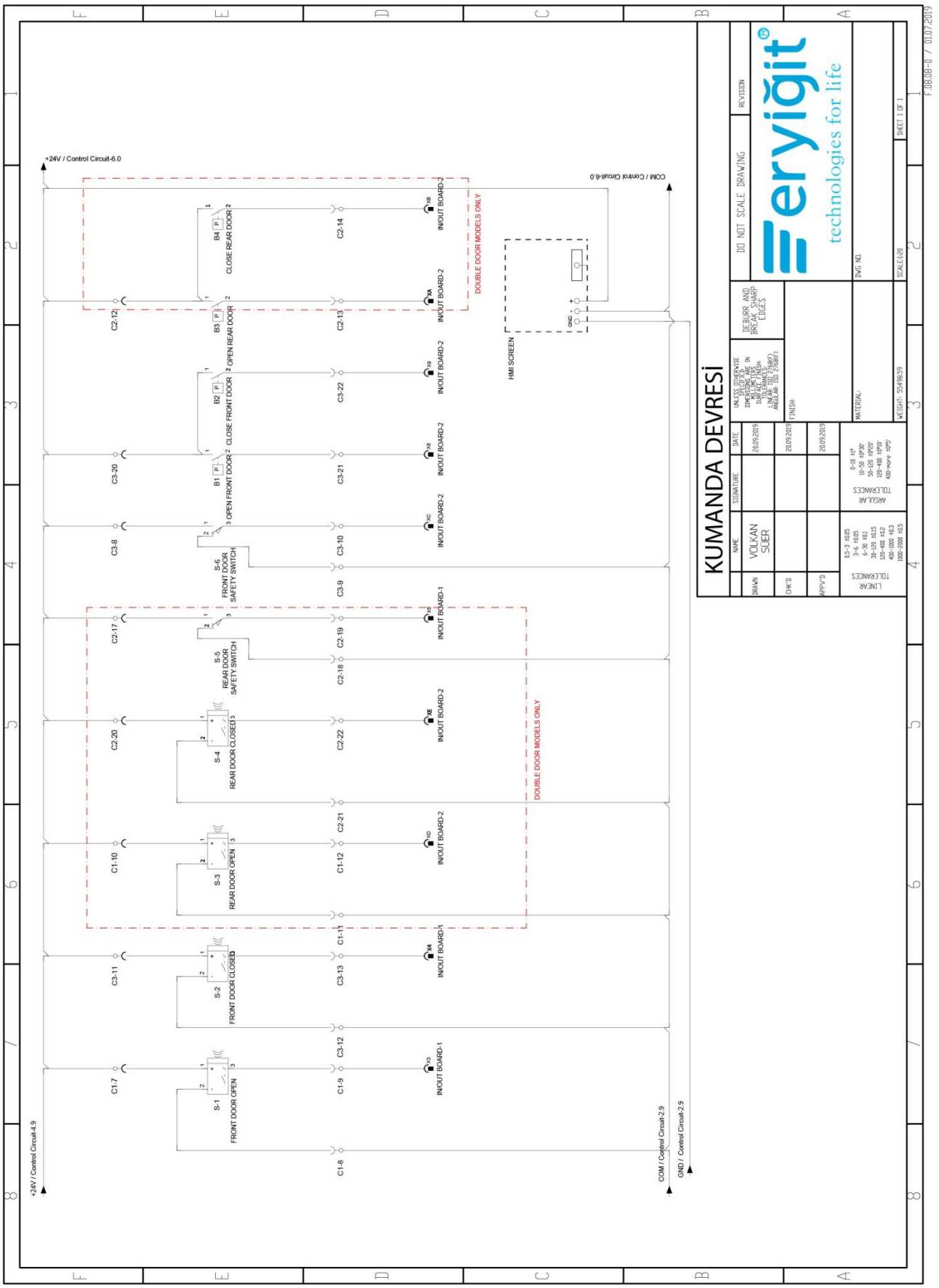
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DOUBLE DOOR MODELS ONLY
HMI SCREEN
S-1 FRONT DOOR OPEN
S-2 FRONT DOOR CLOSED
S-3 REAR DOOR OPEN
S-4 REAR DOOR CLOSED
S-5 REAR DOOR SAFETY SWITCH
S-6 FRONT DOOR SAFETY SWITCH
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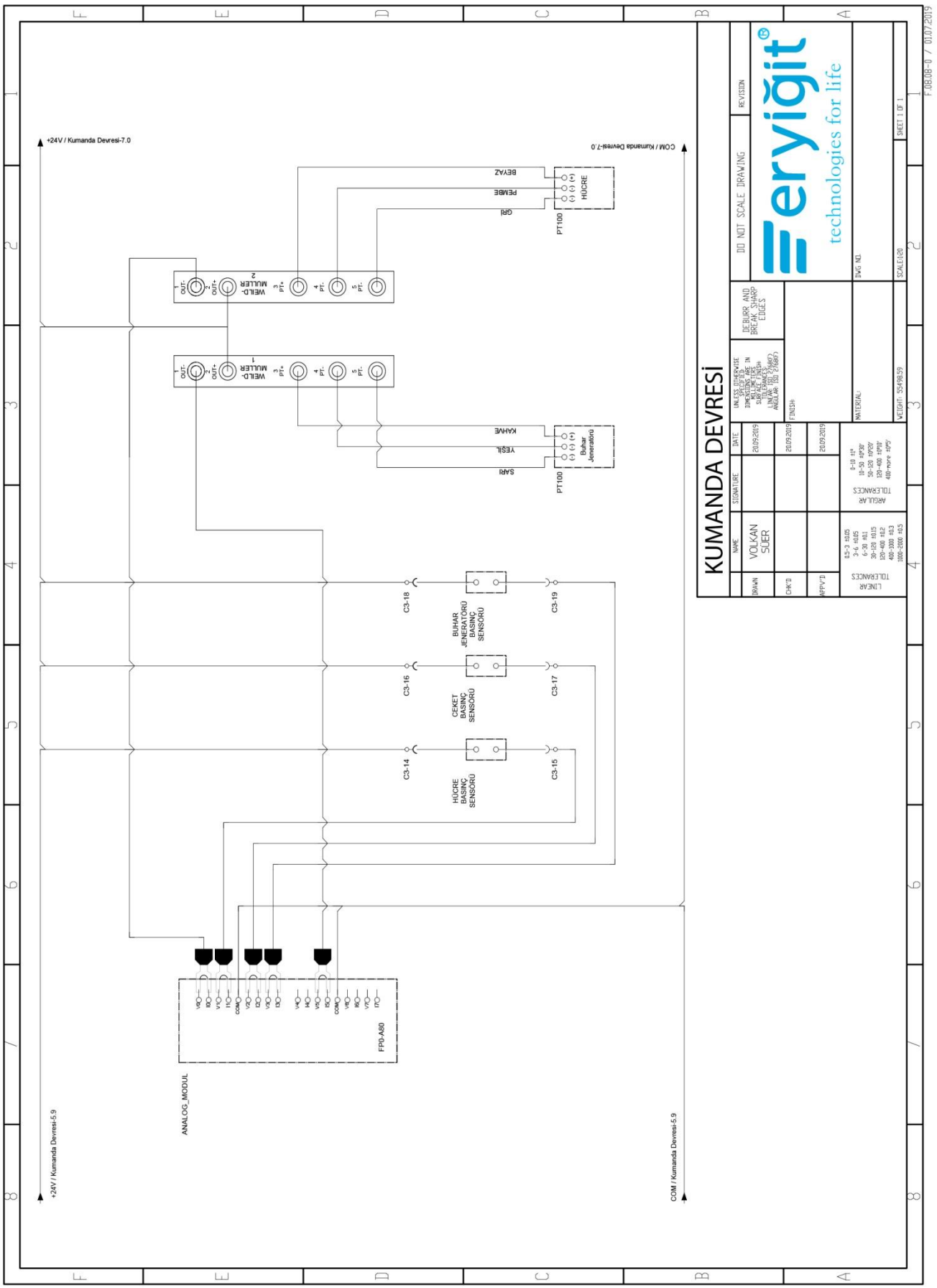
B2 CLOSE FRONT DOOR
B3 OPEN REAR DOOR
B4 CLOSE REAR DOOR
INOUT BOARD-1
INOUT BOARD-2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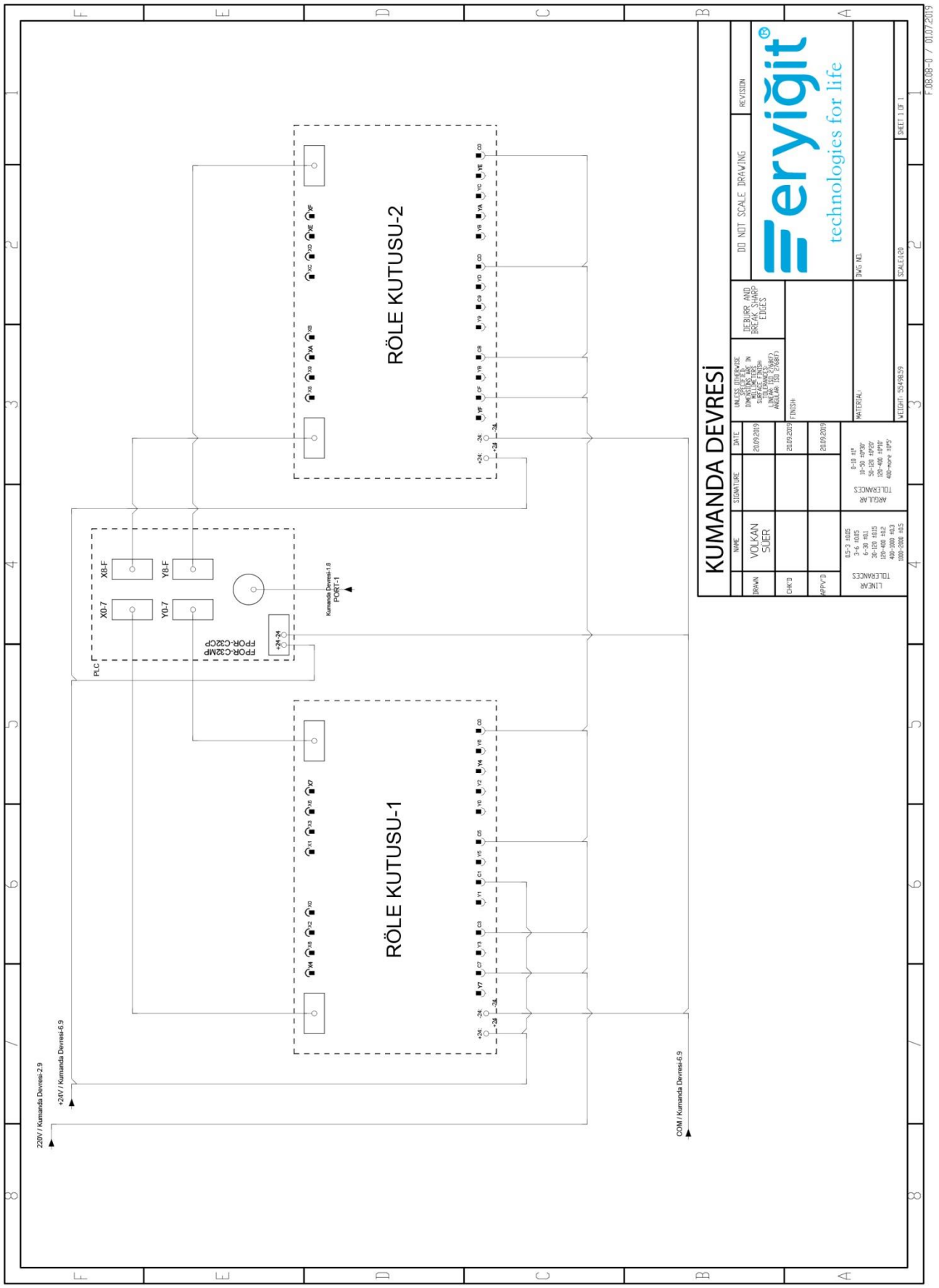
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PORT-1
220V / Kumanda Devresi-2.9
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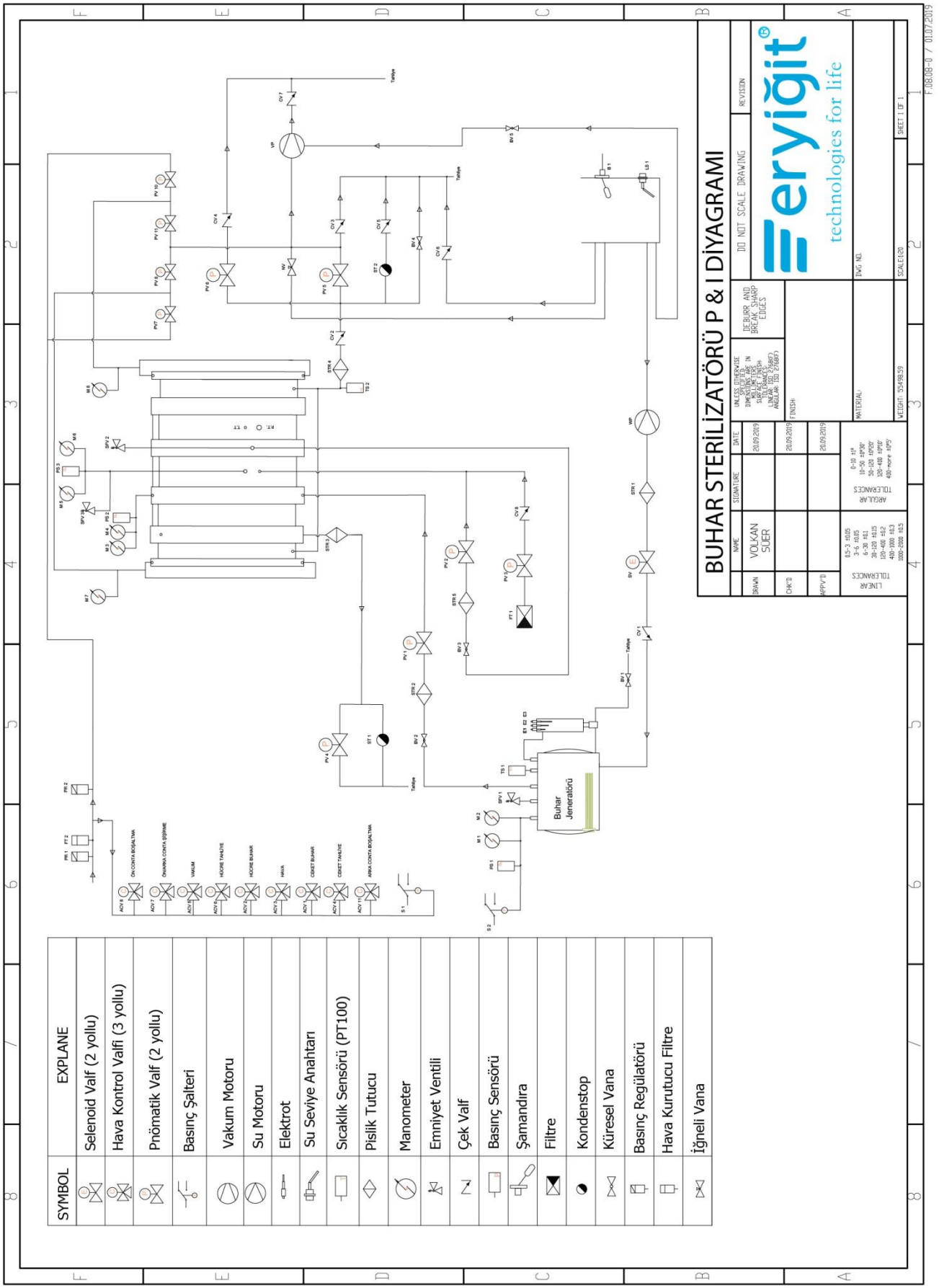
SECTION 5. STEAM STERILIZER FLOW DIAGRAM



CHAPTER 6.STEAM STERILIZER ACCESSORIES AND SPARE PARTS LIST

The sterilizer's CE mark makes the manufacturer responsible for the safety and function of the product meeting the strict requirements set out in the relevant EC directive. Accessories that connect to the sterilizer mechanically, electrically or in any other way must be compatible. As a result, equipment that has been evaluated and approved by the manufacturer can be used with the sterilizer.

ACCESSORY	PRODUCT
Loading Trolley	Loading Trolley 670 * 700 mm
	Loading Trolley 350 * 700 mm
	Loading Trolley 2.000
Loading Rack	Loading Platform 670 * 700 mm
	Loading Platform 350 * 700 mm
	Loading Platform 2.000
Shelf Element	Perforated Shelf Element
STU Basket	Size (WxDxH): 600x300x300 mm.
	Size (WxDxH): 600x300x200 mm.
SPRI Basket	Size (WxLxH) (595 * 395 * 195) mm
	Size (WxLxH) (595 * 395 * 100) mm

SEQUENCE NO	ERYIGIT PART CODE	TYPE OF MATERIAL
1.	T18811500101	Stainless Elbow
2.	T18811500201	Stainless T
3.	T18811500301	Stainless Sleeve
4.	T18811500401	Stainless Nipple
5.	T18811500901	Check valve
6.	T18811501001	Blind Plug
7.	T18811501202	Mini Ball Valve
8.	T18811501203	Ball Valve
9.	T18811501301	Steam trap
10.	T18811501701	Otaklav Water Tank Buoy
11.	T18821501702	Otaklav Water Tank Electric Float
12.	T18811501901	Strainer
13.	T18811502001	Swing Check Valve
14.	T18811502101	Straight Union
15.	T18811502201	Cut Nipple
16.	T18811502107	Rekord
17.	T18811502301	Corner Sleeve coupling
18.	T18811502402	Reduction
19.	T18811502501	Stainless Steel Hose
20.	T18811502601	Kestak Rekoru
21.	T18811502708	Solenoid Valve
22.	T18811502801	Pneumatic Valve
23.	T18811502903	Dual Air Conditioner
24.	T18811502904	Regulator Modular
25.	T18811503005	Chamber / ChamberManometer (-1 + 5 Bar) Gliserinli
26.	T18811503006	Jacket / Jacket Manometer (0-6 Bar) 1/4 "
27.	T18811503007	Generator Manometer (6 Bar) 1/4 "
28.	T18811503008	Air / Air Manometer (-1 + 5 Bar) with Glycerin 1/4"
29.	T18811503010	1/8 " 12 Bar Inlet Manometer
30.	T18811503101	Autoclave Hepa Filter
31.	T18811503203	Kampeni (Company)
32.	T18811503302	9 Coil Group (For Pneumatic Valve)
33.	T18811503402	Safety Valve
34.	T18811503905	Autoclave Water Motor
35.	T18811503906	Autoclave Vacuum motor
36.	T18811504507	Pneumatic Installation Hose
37.	T18811504510	Stainless Steel Pipe
38.	T18811505303	Cover Gasket
39.	T1881150741	Pneumatic Union
40.	T1881150744	Pneumatic Elbow
41.	T1881150747	Pneumatic Union
42.	T18811507413	Pneumatic T
43.	T18811506541	Autoclave Electrical Panel
44.	T18811505906	2,5 mm AVK Orange Terminal
45.	T18811505908	2,5 mm AVK Red Terminal
46.	T18811505911	35 mm Earth Terminal
47.	T18811505920	35 mm Gray Terminal
48.	T18811506001	Buzzer (24V)
49.	T18811506101	16 Female Connector
50.	T18811506102	24 Female Connector
51.	T18811506103	16 Pin Male Connector

52.	T18811506104	24 Pin Male Connector
53.	T18811506205	Panel Socket
54.	T18811506212	3 * 25 Ampere Earthed Plug
55.	T18811506403	TKO 2,5-10 / AVK 2,5 Screw Terminal Shunt
56.	T18811506515	Pin 8 Collector
57.	T18811506516	Role Box
58.	T1881150702	1x6 C Automatic Fuse
59.	T1881150703	1x10 C Automatic Fuse
60.	T1881150705	1x20 C Automatic Fuse
61.	T18811507011	3x63 C Automatic Fuse
62.	T18811507012	3x80 C Automatic Fuse
63.	T18811507013	3x100 C Automatic Fuse
64.	T18811507014	3x125 C Automatic Fuse
65.	T18811507020	0.7-1 Ampere Thermal
66.	T18811507022	4.5-6.3 Amps Thermal
67.	T18811507029	9 Ampere 4 KW Contactor (24 Volt-Water Motor)
68.	T18811507030	9 Amps 4 KW Contactor (Normal Close-Door Motor)
69.	T18811507031	9 Amps 4 KW Contactor (Normal Open-Vacuum Motor)
70.	T18811507033	25 Amps 11KW Contactor (10KW Resistance)
71.	T18811503202	KP35 Presostat Pressure Switch
72.	T18811507038	Phase Protection Relay
73.	T18811506529	Emergency Stop Button
74.	T18811506531	On / Off Switch
75.	T18811506532	Elevator Down / Up Button
76.	T18811507039	Sole Role
77.	T18811507040	Sole Socket
78.	T18811507043	Liquid Level Relay
79.	T1881150712	Door Sensor
80.	T18811507111	Pressure Sensor 4 Bar
81.	T18811507112	Pressure Sensor 6 Bar
82.	T1881150721	PT100 Horizontal Autoclave
83.	T1881150751	PLC
84.	T1881150756	Analog Module Autoclave
85.	T1881150759	PT100 Converter Module
86.	T18811507513	Phase Protection Relay
87.	T18811506528	Printer
88.	T18811504109	Resistance (Autoclave)
89.	T18811500306	Stainless Sleeve
90.	T18831501703	Autoclave Generator Float (Liquid Level)
91.	T18811501601	Autoclave Door Chain
92.	T18811503502	Bearing Stainless
93.	T18811503801	Autoclave Device Door Gear Big Type
94.	T18811503904	0.25 KW Autoclave Door Motor
95.	T18811503807	Reducer
96.	T1881150731	Autoclave Carcass Fixing Chock
97.	T1881150732	Sliding Cover Fixing Chock
98.	T1881150733	Vacuum Motor Fixing Chock
99.	T1881150734	Water Engine Fixing Chock
100.	T1881150737	Autoclave Wheel

SECTION 7. CERTIFICATES

CERTIFICATE

kiwa

EC Certificate

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-10-013

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

ERYİĞİT ENDÜSTRİYEL MAKİNE VE TIBBİ CİHAZLAR
İMALAT İTHALAT İHRACAT İNŞAAT
TİCARET ANONİM ŞİRKETİ

İvedik Organize Sanayi Bölgesi Öz Anadolu Sitesi 1453. Sok. No:3 06370
Ostim, Ankara, Turkey

Products: Steam sterilizers, Washer disinfectors, Oxygen production and storage systems

The products defined at the enclosure which is the part of this certificate and contains one (1) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.2927.10
Date of first issue: 25 February 2010
Date of last issue: 14 November 2019
Revision Number: 08
Expiry Date: 07 February 2021

14 November 2019, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

MDD 93/42/EEC CERTIFICATE

TÜV NORD

CERTIFICATE

Conformity based on full quality assurance
according to directive 2014/68/EU

Certificate No.: 0045/202/9280/Z/0942/18/D/000(00)

Name and address of manufacturer: Eryiğit Endüstriyel Mak. ve Tıbbi
Cih. İml. İth. İhr. İnş. Tic A.Ş.
Özanadolu Sanayi Sitesi 1453 Sok. No:3
06370 / Yenimahalle-Ostim /Ankara

We hereby certify that the manufacturer has established a **quality system** for the manufacturing of pressure equipment according to directive 2014/68/EU. The manufacturer is entitled to mark the pressure equipment produced within the range of the quality system with the following mark:

CE 0045

Tested according to directive 2014/68/EU: Module H EN 13445
Audit report No.: 0045/202/9280/P/0942/18/D/000(00)
Range of products: 3 Bar, 75-2000 Liter for Sterilizer
3 Bar, 50-90 Liter for Autoclave (generator)
Place of manufacture: Özanadolu Sanayi Sitesi 1453 Sok. No:3
06370 / Yenimahalle-Ostim /Ankara
This certificate is valid until: 02.10.2021

Istanbul, 03.10.2018

Attachment: 0045/202/9280/P/0942/18/D/000(00)

Notified Body 0045 for pressure equipment

Ayhan Levent Arslan

Region: Istanbul Tel. +90- 212 293 26 42
Fax +90- 212 293 38 44
e-mail larslan@tuev-nord.de

Member of CEOC

PED 2014/68/EU CERTIFICATE

ZERTİFİKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

BBS

CERTIFICATE

Quality Management System as per
TS EN ISO 9001:2015

In accordance with BBS Belgelendirme Eğitim ve Gözetim Hizmetleri A.Ş. procedures, it is hereby certified that

eryiğit

ERYİĞİT ENDÜSTRİYEL MAKİNA VE TIBBİ CİHAZLAR İMALAT İTHALAT İHRACAT İNŞAAT TİCARET A.Ş.

İvedik Organize Sanayi Bölgesi Öz Anadolu Sitesi 1453. Sk. No: 3
Ostim – Yenimahalle / ANKARA

Applies a management system in line with the above standard for the following scope

Design, Manufacture, Sales And Servicing Of Central Sterilization Units, Steam Sterilizers, Combined Formaldehyde Sterilizators With Steam, Gas Sterilizators With Ethylene Oxide, Hydrogen Peroxide Gas Plasma Sterilizers, Laboratory Type Perpendicular Autoclave, Surgical Washing And Disinfection Devices, Surgery Tables And Traction Kits, Surgery Ceiling Lamps, Gynecologic, Urologic, Delivery And Examination Tables, Hospital Sterilization Stainless Equipments, Ent Chair, Oxygen Production And Storage Systems, Water Treatment Systems And Diesel Engines–Nox Reduction Agent AUS 32.

Certificate No: 9001-01
Initial Certification 06.09.2018
Valid until 05.09.2021

Certification Body at BBS A.Ş.

Ankara, 06.09.2018

This certification was conducted in accordance with BBS A.Ş. auditing and certification procedures and is subject to regular surveillance audits.

IAF TÜRKAK

The authenticity of this certificate may be verified at www.bbsas.com.tr and tbds.turkak.org.tr. The authenticity may also be checked with the QR Code above.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Kabil Caddesi 1328 Sokak No:8/9 TR-06460 ÇANKAYA / ANKARA
www.bbsas.com.tr

ISO 9001:2015 CERTIFICATE

CERTIFICATE

TÜRKAK

kiwa

eryiğit

ERYİĞİT ENDÜSTRİYEL MAKİNE VE TIBBİ CİHAZLAR
İMALAT İTHALAT İHRACAT İNŞAAT TİCARET A.Ş.

İVEDİK ORGANİZE SANAYİ BÖLGESİ ÖZ ANADOLU SİTESİ 1453. SOK. NO:3 OSTİM
YENİMAHALLE – ANKARA – TURKEY

with a scope of

DESIGN, MANUFACTURE AND SERVICING OF CENTRAL STERILIZATION UNITS, STEAM STERILIZERS, HYDROGEN PEROXIDE GAS PLASMA STERILIZERS, LABORATORY TYPE PERPENDICULAR AUTOCLAVE, SURGICAL WASHING AND DISINFECTION DEVICES, SURGERY TABLES AND TRACTION KITS, SURGERY CEILING LAMPS, GYNECOLOGIC, UROLOGIC, DELIVERY AND EXAMINATION TABLES, HOSPITAL STERILIZATION STAINLESS STEEL EQUIPMENTS ENT CHAIR, OXYGEN PRODUCTION AND STORAGE SYSTEMS

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded" "4.4.2" "7.3.2" "7.3.3" "7.3.9.2"

EN ISO 13485:2016

Certificate No : M 7762
Initial Certification Date : 28 January 2010
Certification Date : 08 January 2019
Expiration Date : 07 January 2022

General Manager

Kiwa Certification Services Inc.
İTOSB 9. Caddesi No. 15 Tepeören Tuzla - İstanbul - Turkey
Tel: + 90 216 593 25 75 Faks: + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 08 January 2019 - R 06

ISO 13485:2016 CERTIFICATE

ZERTİFİKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

BBS

CERTIFICATE

Environmental Management System as per
TS EN ISO 14001:2015

In accordance with BBS Belgelendirme Eğitim ve Gözetim Hizmetleri A.Ş. procedures, it is hereby certified that

eryiğit

ERYİĞİT ENDÜSTRİYEL MAKİNA VE TIBBİ CİHAZLAR İMALAT İTHALAT İHRACAT İNŞAAT TİCARET A.Ş.

İvedik Organize Sanayi Bölgesi Öz Anadolu Sitesi 1453. Sk. No: 3
Ostim – Yenimahalle / ANKARA

Applies a management system in line with the above standard for the following scope

Design, Manufacture, Sales And Servicing Of Central Sterilization Units, Steam Sterilizers, Combined Formaldehyde Sterilizators With Steam, Gas Sterilizators With Ethylene Oxide, Hydrogen Peroxide Gas Plasma Sterilizers, Laboratory Type Perpendicular Autoclave, Surgical Washing And Disinfection Devices, Surgery Tables And Traction Kits, Surgery Ceiling Lamps, Gynecologic, Urologic, Delivery And Examination Tables, Hospital Sterilization Stainless Equipments, Ent Chair, Oxygen Production And Storage Systems, Water Treatment Systems And Diesel Engines–Nox Reduction Agent AUS 32.

Certificate No: 14001-02
Initial Certification 06.09.2018
Valid until 05.09.2021

Certification Body at BBS A.Ş.

Ankara, 06.09.2018

This certification was conducted in accordance with BBS A.Ş. auditing and certification procedures and is subject to regular surveillance audits.

IAF TÜRKAK

The authenticity of this certificate may be verified at www.bbsas.com.tr and tbds.turkak.org.tr. The authenticity may also be checked with the QR Code above.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Kabil Caddesi 1328 Sokak No:8/9 TR-06460 ÇANKAYA / ANKARA
www.bbsas.com.tr

ISO 14001:2015 CERTIFICATE

Certificate

to

ERYİĞİT End. Mak. Tıbbi Cihazlar İml. İth. İhr. İnş. AŞ.
İVOGSAN 1453. Sok. No: 3 Ostim
06378 Ivedik - Ankara / TURKEY

manufacturing
the series of sterilizers (160 litres to 840 litres):
GOLDBERG
Sterilization equipment:
Single Door: 160S, 250S, 300S, 422S, 550S, 675S, 840S
Double Door: 160D, 250D, 300D, 422D, 550D, 675D, 840D
It is hereby certified that the above named machines
fulfill the requirements and therefore the type test of EN 285 (2009)
„Sterilization – Steam sterilizers – Large sterilizers "
Identification Number: 99302 Schwerin, 14.10.2014

Prof. Dr. med. H.-P. Werner
Head of Scientific-Technical Affairs
Dr. med. univ. Sebastian Werner
Managing Director

EN 285 TYPE TEST CERTIFICATE

BEGLAUBIGTE KOPIE

Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

№ 15741

ACCREDITATION

The Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) confirms that the

HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH
Bornhövedstr. 78
19055 Schwerin
Germany

is competent under the terms of

EN ISO/IEC 17025, the Council Directives 93/42/EEC and 90/385/EEC

for

biological, chemical, microbiological, microbiological-hygienic, physical and physical-mechanical testing on medical devices including disinfectants, washer-disinfectors, sterilizers and on washing-disinfection and sterilization methods including physical testing; environmental monitoring.

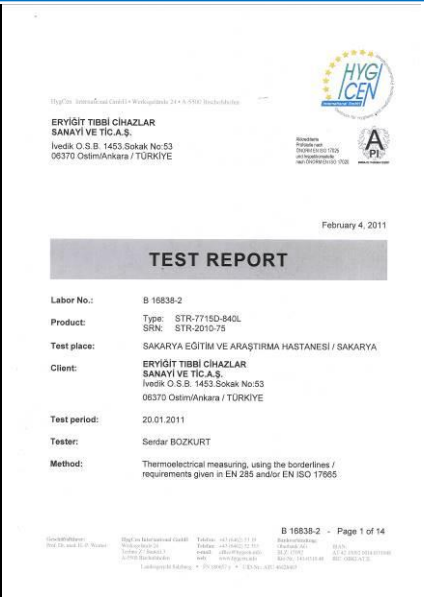
This accreditation is valid up to 2013-10-18.

This document is valid only in conjunction with the accreditation notice which contains the binding information on the accreditation. The scope of the accreditation is specified in the annex in force of the accreditation notice and can be found on www.zlg.de, tab accredited bodies, laboratories.

Registration number ZLG-P-715.98.13

Bonn, 06.02.2009

ACCREDITATION CERTIFICATE EN 285



ERYİĞİT TIBBİ CİHAZLAR SANAYİ VE TİC.A.Ş.
İvedik O.S.B. 1453.Sokak No:53
06370 Ostim/Ankara / TÜRKİYE

February 4, 2011

TEST REPORT

Labor No.:	B 16838-2
Product:	Type: STR-7715D-840L SRN: STR-2010-75
Test place:	SAKARYA EĞİTİM VE ARAŞTIRMA HASTANESİ / SAKARYA
Client:	ERYİĞİT TIBBİ CİHAZLAR SANAYİ VE TİC.A.Ş. İvedik O.S.B. 1453.Sokak No:53 06370 Ostim/Ankara / TÜRKİYE
Test period:	20.01.2011
Tester:	Serdar BOZKURT
Method:	Thermoelectrical measuring, using the borderlines / requirements given in EN 285 and/or EN ISO 17665

B 16838-2 - Page 1 of 14

VALIDATION TEST REPORT

kiwa certified ISO 13485

kiwa certified KIWA CE MARK

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cd. No:15 Tepeören Tuzla – İstanbul / TÜRKİYE

SECTION 8. SERIES NO LABEL EXAMPLE

Eryiğit Endüstriyel Makina ve Tıbbi Cihazlar İml. İth. İhr. İnş. Tic A.Ş.	**Adres /** *Address*	İvedik Organize Sanayi Bölgesi Öz Anadolu Sitesi 1453 Sok. No:3 Ostim, Yenimahalle, Ankara, Türkiye
	Tel / *Phone*	+90.312.395 57 95
	Faks / *Fax*	+90.312.395 57 96
	E-posta /*E-mail*	info@eryigit.com.tr
	Web	www.eryigit.com.tr

BUHARLI STERİLİZATÖR
STEAM STERILIZER

MODEL *Model*	GOLDBERG® _	SN **SERİ NO** *Serial No*	20__/01-__
HACMİ *Volume*	_ L	**GÜCÜ** *Power*	3x 220/380 V AC, E+Z, 50 Hz, _A, _ kW
Toplam Ağırlık *Total Weight*		_ kg	
	__/20__		

	SERİ NO *Serial No*	**ÇALIŞMA BASINCI** *Working Pressure*	**ÇALIŞMA SICAKLIĞI** *Working Temp*	**TEST BASINCI** *Testing Pressure*	**VAKUM BASINCI** *Vacuum Pressure*
HÜCRE *Chamber*	H/01-__	2,8 Bar	140 °C	5 Bar	70 mBar
JENERATÖR *Generator*	J/01-__	3 Bar	150 °C	7 Bar	-

Kullanma Kitabını Okumadan Cihazı Çalıştırmayınız!
Do not power on the device before you read the instructions

3N ~	**EN 285 TİP TESTİ TYPE TEST**	CE 0045 Basınçlı Ekipman Direktifi Pressure Equipment Directive 2014/68 EU	CE 1984 Medikal Cihaz Direktifi Medical Device Directive 93/42 EEC

ISO 9001 & ISO 13485& ISO 14001

F.02.23-1 /05.02.2021

Warranty Certificate

WARRANTY CONDITIONS

1. The product; It is guaranteed for 1 year between the dates written in the document (according to the contract provisions) against material, workmanship and production defects from the date of delivery with invoice.
2. During the warranty period, maintenance, repair, replacement of parts, etc. by persons not officially authorized by ERYİĞİT TIBBİ CİHAZLAR A.Ş. In the event of an intervention and / or detection for transactions, the device is out of warranty.
3. Damages and failures that may arise from interventions other than the authorized service are not covered by the warranty. Labor services within the warranty period are free of charge.
4. Repair time; It starts after the day of written notification to our authorized dealer or our company. The elapsed time will be added to the warranty period.
5. After delivery; Damages and failures caused by scratches and breaks of the outer body, plastic parts and PLC screen, and usage errors during loading, unloading and transportation are not covered by the warranty.
6. Fire and lightning strikes, voltage drop or surplus; Faulty electrical installation and incorrect connection, use of a voltage different from the voltage specified on the product's label are not covered by the warranty.
7. Out of warranty faults are remedied for a fee. No claims and compensation can be claimed in cases out of warranty.
8. The malfunction will be intervened within 48 hours following the failure notification and the device will be operational within 10 working days.
9. Detection of malfunctions and needs will be made by the technical staff of our company.
10. The issues regarding the elimination of faults on site or at authorized services are subject to the approval of the user and / or the administration.
11. No labor fee is requested for the periodic maintenance defined in the contracts.
12. The consumers will be intervened if they notify Eryiğit Medical Devices Inc. of their disputes with Authorized Services that provide maintenance and repair services in writing.
13. The device has Maintenance-Repair and Spare Parts Supply Warranty for a fee for 10 (ten) years following the end of the warranty period.
14. At the end of the warranty period, in line with the consumer's request, a Maintenance-Repair Contract can be made in periods.
15. Administrations; Our company is not responsible for possible risks arising from not using original spare parts in our production devices after the end of the warranty period.
16. Items not covered by the warranty are included in the items written in the "User Manual" supplied with the device.
17. This guarantee remains valid if the consumer and / or consumer institution fulfills its responsibilities to the customer.
18. The warranty certificate is issued as two complete originals, no tampering can be made on the documents and the serial number label of the device.
19. During the warranty period, the bill of materials must be kept. Materials whose invoices are not submitted are deducted from the guarantee provision.
20. The use of this Guarantee Certificate is subject to the Law No. 4077 and Authorized by the T.R. Ministry of Industry and Trade, General Directorate of Protection of Consumers and Competition.

TYPE OF PROPERTY : Steam Sterilizer
BRAND : GOLDBERG®
MODEL :GOLDBERG
SERIAL NUMBER :
DELIVERY LOCATION:

SELLER : ERYİĞİT END.MAK.VE TIBBİ CİH.İML.İTH.İHR.İNŞ.TİC.A.Ş.
ADRESS : İVEDİK OSB ÖZANADOLU SAN.SİT.1453.SOK.NO:3 OSTİM, YENİMAHALLE/ANKARA
TEL : 0312 395 57 95
FAX : 0312 395 57 96
Web : www.eryigit.com.tr
E-mail : servis@eryigit.com.tr / info@ eryigit.com.tr

INVOICE DATE :
BILL NUMBER :

Date :
STAMP / SIGNATURE :

eryiğit®
technologies for life

İvedik OSB Özanadolu Sanayi sitesi 1453 Sokak, No:3 06370 Ostim, Yenimahalle / Ankara
Tel : +90.312.395 57 95
Fax : +90.312.395 57 96
E-mail : info@eryigit.com.tr
Web : www.eryigit.com.tr

CERTIFICATE

kiwa

eryiğit

ERYİĞİT ENDÜSTRİYEL MAKİNE VE TIBBİ CİHAZLAR İMALAT İTHALAT İHRACAT İNŞAAT TİCARET A.Ş.

İVEDİK ORGANİZE SANAYİ BÖLGESİ ÖZ ANADOLU SİTESİ 1453. SOK. NO:3 OSTİM YENİMAHALLE – ANKARA – TURKEY

with a scope of

DESIGN, MANUFACTURE AND SERVICING OF CENTRAL STERILIZATION UNITS, STEAM STERILIZERS, HYDROGEN PEROXIDE GAS PLASMA STERILIZERS, LABORATORY TYPE PERPENDICULAR AUTOCLAVE, SURGICAL WASHING AND DISINFECTION DEVICES, SURGERY TABLES AND TRACTION KITS, SURGERY CEILING LAMPS, GYNECOLOGIC, UROLOGIC, DELIVERY AND EXAMINATION TABLES, HOSPITAL STERILIZATION STAINLESS STEEL EQUIPMENTS ENT CHAIR, OXYGEN PRODUCTION AND STORAGE SYSTEMS

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"6.4.2" "7.5.2" "7.5.5" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 7762
Initial Certification Date	: 28 January 2010
Certification Date	: 08 January 2019
Expiration Date	: 07 January 2022

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-E8A8-8605

Last Modified: 08 January 2019 - R 06

Steam Sterilizer
Goldberg 120S

eryiğit MEDICAL DEVICES

Technical Datasheet

ERYIGIT's GOLDBERG steam sterilizer is offered in a prevacuum configuration and is designed and manufactured for fast and efficient sterilization of textile material, surgical instruments, dressing tools, rubber materials and liquids in a glass container in healthcare facilities.

Size of Chamber	
Chamber Volume	120 Lt.
Chamber Depth	700 mm
Chamber Width	350 mm
Chamber Height	520 mm
Basket Capacity*	2 pcs
STU Capacity **	1 pc

** Basket size (ISO): 600x400x200 mm (LxWxH)*

*** Basket/container size (STU): 600x300x300 mm (LxWxH).*

Dimensions	Single Door	Double Door
Door Type		***Vertical Sliding Door***
Depth	1100 mm	N/A
Width	800 mm	N/A
Height	1800 mm	N/A
** Single Door Option is available only.*		
Empty Weight	~580 Kg	N/A
Packaged Weight	~650Kg	N/A

GOLDBERG 120S steam sterilizer is designed and manufactured in compliance with the following requirements and standards:

Medical Device Directive	: 93/42/EEC as amended by directive 2007/47/EC
Device Classification	: Class IIb, acc. To EC MDD 93/42/EEC 2007/47/EC (Annex IX)
Low Voltage Directive	: EN 60601-1; EN 61010-1; EN 61010-2-040
EMC Directive	: EN 60601-1-2; EN 61326-1
Pressure Equipment Directive	: PED 2014/68 EU
Sterilization – Steam sterilizers – Large sterilizers	: EN285
Quality Management System Requirements	: EN - ISO 9001:2015
Medical Devices – Quality management systems – Requirements for regulatory purposes	: ISO 13485:2016
Environmental Management Systems – Requirements with guidance for use	: ISO 14001:2015

"Type" tests of GOLDBERG steam sterilizers are performed and certified according to the directives of EN 285 and TS EN 17665-1-2 by The German accreditation company HYGCEN GmbH.

Device	
Control System	PLC (Programmable Logic Controller)
Operation Mode	Fully Automatic / Button Command and touch screen
Display Type	Color TFT, LCD Touch Screen
Display Sizes Available	7,0"(standard) / 10,0" (optional)
Key Pad	Touchscreen
Printer	40 Character/line, integrated thermal printer
Communication	RS232 Port/USB Port
Warning System	Visual & Audio & Printed
Data Storage	1000 cycles
Monitoring	Addition to Touchscreen, analogue gauges for chamber, jacket, generator and air pressure
Mobility	Easy positioning on 4 castors (2 x swivel) and firm fixing on suspension legs
Steam Control	Through pneumatic and electric valves

Standard Programs	
Medical & Surgical Instruments (134°C	~ 60 min
Textile Materials (134°C)	~ 60 min
Rubber Articles (121°C)	~ 80 min
Liquids in Glass Container (121°C)	~ 60 min
Silicone Implants (134°C)	~ 80 min
Flash (134°C)	~ 20 min
Prion (134°C)	~ 90 min
Bowie & Dick Test (134°C)	~ 45 min
Vacuum Leak Test	~ 25 min
Customized Program Capacity	20

Process times are load-dependent and approximate. They refer to full process including drying with an average load.

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Safety & Quality Features

- √ Protects operator from electrical current leaks.
- √ Short circuit protection.
- √ Safety valve.
- √ Hepa filter for air filtration.
- √ Water level control with electrodes in generator.
- √ Water level buoy (at water tank).
- √ Steam traps for sensitive steam drainage.
- √ Leak test.
- √ Password protection.
- √ Sensors against obstructions on the doors way.
- √ Pressured door locks.
- √ Unable to open both doors at once in Septic-Aseptic models.
- √ Emergency stop button.

Temperature	
Range	110°C - 141°C (chamber)
Measurement	PT 100 (DIN Class A) Sensors
Location	Chamber, Generator

Pressure	
Measurement	Pressure Transducers
Location	Chamber, Jacket, Generator

Vacuum	
Source	Pump, liquid ring (2.2KW)
Capacity	60 mbar
Pre-Vacuum	Yes

Construction	
Frame/Carcase	Electrostatic powdered profile steel AISI 304 stainless steel (optional)
Outer Panel	AISI 304 stainless steel
Chamber	6.0 mm, AISI 316 L/Ti stainless steel
Jacket	3 mm, AISI 304 L stainless steel, partial cover AISI 316L stainless steel is optional Full cover jacket is optional*
Door	6 mm, AISI 304 stainless steel
Panels Surrounding	AISI 304 stainless steel
Piping	brass AISI 304 stainless steel
Chamber Polishing	Electro polishing is Optional*

Installation Requirement	
Power	30 kW, 3 Phase / 400 VAC ±10
Water	RO treated deionized water for high performance

Chamber	
Test Pressure	5 Bar

Steam Generator	
Capacity	50 Lt
Water Level Protection	CRES* / AISI 304 steel box
Power (3 Phase, 400 ±10 VAC)	20 KW
Test Pressure	7 Bar

** CRES : Corrosion Resistant Stainless Steel*

Consumption	
Electricity	10 kW/cycle
Water (Approximate)	~170 Lt/cycle

Steam	
Type	97% Saturated Steam at Abs. Pressure
Source	Built in Steam Generator Central Steam System is optional*
Side of Applied Steam	Lateral

Optional Accessories
2 Shelves including chamber rails
Cart Set (Transport + Loading) with adjustable height option
Single Transport Trolley (Optional Height Adjusting)
Single Loading Cart (AISI 304 Stainless Steel)
STU Basket (AISI 304 Stainless Steel)

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Feeding Water Requirements *	
Residue on evaporation	≤ 10 mg/L
Silicate (SiO2)	≤ 1 mg/L
Iron	≤ 0,2 mg/L
Cadmium	≤ 0,005 mg/L
Lead	≤ 0,05 mg/L
Heavy metals other than iron, cadmium, lead	≤ 0,1mg/L
Chloride (Cl)	≤ 2 mg/L
Phosphate (P2O5)	≤ 0,5 mg/L
Conductivity (at 25°C)	≤ 5 µS/cm
pH Value (degree of acidity)	5 to 7,5
Appearance	Free of sediment, clear, colorless
Hardness (Σ Earth Alkali Ions)	≤ 0,02 mMol/L

** Water quality should be checked by standard analitical test methods by the institution which utilizes the sterilizer.*

Drainage	
Water	Inclined metal pipe to be installed onsite with at least 2 meters of length (diameter: 2" - 3")
Steam (Condensed)	Steam Trap (built in)
Air	Central Air System of Hospital 6 bar pressure

Installation Conditions

At least 60 cm. space is needed on both lateral sides of the device to provide an effective technical service. Exhaust fan or ventilation funnel needs to be placed above the device for an effective evacuation of heat.

For more information, please contact:

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