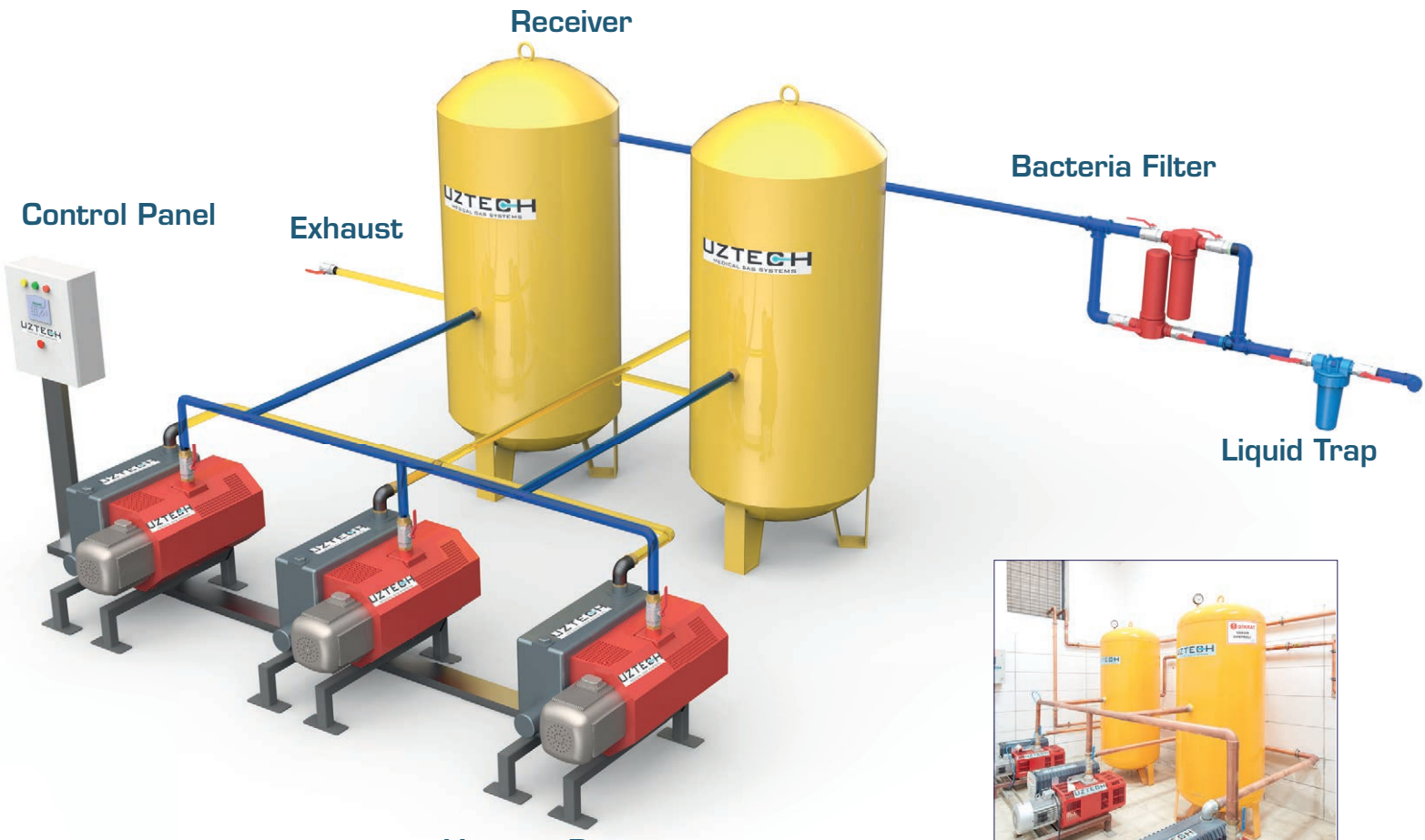


Medical Vacuum

It is critically important to provide a continuous supply of medical vacuum to a medical gas pipeline systems to aspirate fluids in OT, ICU and patient rooms.

UZTECH medical vacuum systems are manufactured in compliance with HTM 02-01, HTM 2022, MDD 93/42/EEC, EN ISO 7396-1 and C11 international standards .

UZTECH medical vacuum plants are equipped with robust, high quality lubricated rotary vacuum pumps which are PLC controlled for equal aging.

Digitally signed by Vidiborschii Vladimir
Date: 2022.07.29 11:28:59 EEST
Reason: MoldSign Signature
Location: Moldova

VAC Plus Vertical – Central Vacuum Station:

- Designed to supply a continuous medical vacuum of healthcare facilities.
- PLC controlled full automatic system
- Compact design
- Medical type high efficiency bacteria filters
- Lubricated rotary vane vacuum pumps
- Sliding trays for easy access of pumps

Model No	VRD-42	VRT-43	VRD-102	VRT-103	VRD-202	VRT-203
System Capacity (m^3/h) (50 hz)	47x2	47x3	100x2	100x3	200x2	200x3
Power (kW) (50 Hz)	1,10x2	1,10x3	2,20x2	2,20x3	4,00x2	4,00x2
Pump Qty	2	3	2	3	2	3
Tank Capacity	500	500	1000	1000	1500	1500
Bacteria Filter Qty	1 pc	1 pc	1 pc	2 pc	2 pc	2 pc
Liquid Trap	1 pc	1 pc	1 pc	1 pc	1 pc	2 pc
Inlet hose dia.	1"	1"	1"1/4	1"1/4	2"	2"
Outlet hose dia.	1"	1"	1"1/2	1"1/2	2"	2"
Bed Qty	70	50-90	90-180	150-200	160-300	160-350
Article Code	66.1344	66.1498	66.1343	66.1396	66.1118	66.1500

VAC Plus Compact – Central Vacuum Station:

- Designed to supply a continuous medical vacuum of healthcare facilities
- PLC controlled full automatic system
- Compact tank top design
- Suitable for low height medical gas plant rooms
- Medical type high efficiency bacteria filters
- Lubricated rotary vane vacuum pumps

Model No	VYD-42	VYT-43	VYD-102	VYT-103	VYD-202	VYT-203
System Capacity (m^3/h) – (50 Hz)	47x2	47x3	100x2	100x3	200x2	200x3
Power (kW) – (50 Hz)	1,10x2	1,10x3	2,20x2	2,20x3	4,8x2	4,8x3
Pump Qty	2	3	2	3	2	3
Tank Capacity	500	500	1000	1000	1000	1000
Bacteria Filter Qty	1 pc	1 pc	1 pc	2 pcs	2 pcs	2 pcs
Liquid Trap Qty	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc
PLC Qty	1	1	1	1	1	1
Inelt hose dia.	1"	1"	1"1/4	1"1/4	2"	2"
Outlet hose dia.	1"	1"	1"1/2	1"1/2	2"	2"
Bed Qty	70	50-90	90-180	150-200	160-300	160-350
Article Code	66.1120	66.1501	66.1119	66.1502	66.1566	66.1567

PLC Control Panel:

- Designed to control the vacuum pumps of central vacuum stations
- Fully automatic digital control unit

Model No	Pump T.	Cap. m3/h	Dimensions(mm)	Article Code
3301.10	Single	25 - 40	350x160x530	66.1131
3301.20	Double	65 - 100	350x160x530	66.1132
3301.30	Triple	150 - 200	350x160x530	66.1133

Bacteria Filter Set:

- 100 m^3/h flow capacity
- Integrated by-pass valves and discharge system
- Bacteria filtration of 30 micron

Model No	Pump Type	Article Code
3200.10	Single	66.1129
3200.20	Doble	66.1130

Liquid Trap:

- High efficiency trap designed to drain liquids in vacuum pipeline
- 1.5 L capacity
- Inlet and outlet valves included

A.C.: 66.1128

Vacuum Tank:

- Designed to use in central vacuum stations
- Different capacities for different stations
- Vertical or horizontal types avaliable
- Made of highly durable steel material

Model No	Capacity (l)	Wall Thickness	Diameter	Length
3350.05	500 L	5 mm	630 mm	1800 mm
3350.75	750 L	5 mm	750 mm	1800 mm
3350.10	1000 L	6 mm	850 mm	1920 mm
3350.15	1500 L	6 mm	1100 mm	2200 mm

Vacuum Pumps

The lubricated rotary vane pumps are designed to be used in a wide range of industrial and healthcare applications. They can run continuously from atmospheric pressure to ultimate vacuum.

- Specially designed for medical applications
- Stable and longlife pumps
- Lubricated rotary vane vacuum pumps
- Single stage
- High pumping speed even at low pressure
- Integrated oil mist filter on the exhaust
- Pumps can run continuously from atmospheric pressure to ultimate vacuum
- Silent and very robust pumps
- Options; Oil level switch, PT100 temperature sensor

Maintenance Kits

Usual maintenance (EC): 3000 h or 24 months

- Inspection / cleaning
- Oil change
- Oil filter replacement
- Oil separating cartridge(s) change
- Inlet valve overhaul
- Gas ballast filter change

- Options; Oil level switch, PT100 temperature sensor

Maintenance Kits

Preventive maintenance (MP): 12 000 hours

- Radial shaft seals change
- Sliding rings change
- Vanes replacement*
- End cover gaskets replacement
- Automatic drain + gaskets replacement
- Rubber feet replacement
- Coupling ring overhaul

Model No	*Nominal Flow*		*Motor Power*		*Weight*	*3 000 hours or 24 months, Maintenance Kits*	*12 000 hours Maintenance Kits*
	$m^3.h^{-1}$		*Kw*				
	50 Hz	*60 Hz*	*50 Hz*	*60 Hz*	*kg*	*Model no*	*Model no*
VPS-25	*30*	*35.3*	*0,75*	*0,9*	*39*	*VSM-00*	*VSM-10*
VPS-40	*47.7*	*56*	*1,1*	*1,32*	*52*		
VPS-70	*64.3*	*72.2*	*1,5*	*1,8*	*75*	*VSM-01*	*VSM-11*
VPS-100	*96*	*115*	*2,2*	*2,70*	*85*	*VSM-02*	*VSM-12*
VPS-150	*132*	*156*	*3*	*3,6*	*154*	*VSM-03*	*VSM-13*
VPS-200	*198*	*240*	*4*	*4,8*	*140*	*VSM-04*	*VSM-14*
VPS-300	*293*	*354*	*5,5*	*6,6*	*162*	*VSM-05*	*VSM-15*

AGM-00

AGM-01

Mini Vacuum Station

- Ready to run compact size vacuum plants
- Lubricated rotary vane vacuum pump
- Standard suction network inlet
- Bacteria filter with aspiration (optional)
- Liquid trap (optional)

Model No	*AGM-00*	*AGM-01*
Nominal Capacity (m^3.h-1) 50 Hz	*25*	*2x10*
Power (kW) 50 Hz	*0,75*	*2x0,35*
Tank Capacity (L)	*70*	*70*
Noise Level dB (A)	*60*	*60*
Oil Capacity(L)	*1,5*	*1,5*
Weight (kg)	*85*	*85*

AGS-01
AGS-02

AGS-04
AGS-05

Anaesthetic Gas Scavenging System, Single and Double

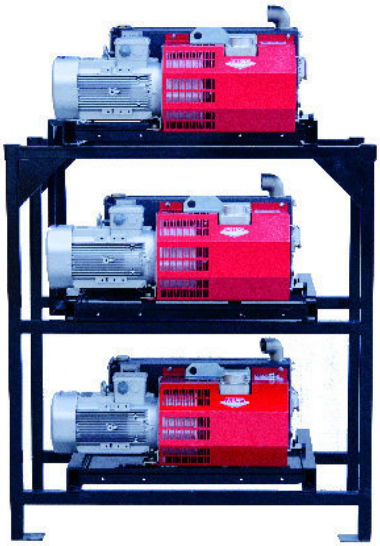
AGSS is used for discharging the anesthetic gas from OT. UZTECH AGSS is CE marked and manufactured according to MDD 93/42/EEC and comply with HTM 02-01.

- Single and double blower versions are available.
- Oil-free blowers are suitable for continuous run

Model No	*AGS-00*	*AGS-01*	*AGS-02*	*AGS-03*	*AGS-04*	*AGS-05*
Capacity	*24m3/h*	*80m3/h*	*130m3/h*	*2x24m3/h*	*2x80m3/h*	*2x130m3/h*
Power kw	*1,3*	*1,75*	*3,4*	*2x0,75*	*2x1,75*	*2x3,4*
Vacuum	*200 mbar*	*200 mbar*	*200 mbar*	*200 mbar*	*200 mbar*	*200 mbar*
Inlet Dia mm	*38*	*50,8*	*50,8*	*31.75*	*38*	*50,8*
Outlet Dia mm	*44*	*44*	*60*	*44*	*44*	*60*
Weight	*40*	*50*	*60*	*100*	*120*	*150*

USER MANUAL

CENTRAL VACUUM STATIONS



CE 2292

ÜZÜMCÜ

CONTENTS

CE Declaration of Conformity

This device conforms to the requirements specified in TS EN ISO 10079-1 "Medical suction equipment - Part 1: Electrically powered suction equipment" and MDD/93/42/EEC Medical Devices Directive.

Notified Body Information

Name/ Number: UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. /2292
Address : Mutlukent Mahallesi 2073 Sokak No:10 Ümitkoy-Ankara TURKEY
Phone :+90 312 443 03 90
Fax :+90 312 443 03 76
E-Mail: info@udemltd.com.tr

Patent

Trade name and brand qualification are held by UZUMCU A.Ş.

Product Lifespan

The product lifespan of the device as determined by the Ministry of Industry and Trade is 10 years.

Guarantee Period

UZUMCU brand portable suction units, including all parts, are under warranty for 2 (two) years against material defects, faulty workmanship and manufacturing defects provided that they are used as shown in user manuals. However, the following are not under warranty:

1. Damages and failures that result from misuse,
2. Damages and failures that occur during loading & unloading and transportation after the delivery of the product to the customer,
3. Damages and failures that result from under- or over-voltage, faulty electrical installation or using at a voltage different from the one specified in the product label,
4. Failures that result from using the product in contravention of the matters contained in user manuals.

Thank you for purchasing UZUMCU brand portable suction unit. Our product has been meticulously designed and produced for offering quality and performance to you in the best possible way. Please carefully read all information about the operation and safety of this equipment and keep this manual as a reference guide.

This manual explains the steps of Installation, Use, Cleaning and Maintenance & Repair for UZUMCU brand portable suction units.

Points to Consider During Handling and Transportation

Please follow the instructions on equipment boxes during handling and transportation.

Matters Related to Maintenance and Repair

Please call the authorized service of the equipment in case of situations that require Maintenance and Repair.

Information about Connection and Assembly

Please refer to the following parts for connection and assembly information.

In order to use and service the portable suction unit by ensuring patient and user safety:

- Before putting the central vacuum plant into service, make sure that this user manual is read and understood with warnings and explanations.
- The purchaser is responsible for ensuring that personnel responsible for the use or maintenance of the central vacuum plant are informed about the contents of this user manual.
- Keep the user manual in a place where the user can easily find it. Do not use the central vacuum plant for purposes other than those described in this manual.
  • Maintain the central vacuum plant regularly, at the intervals specified in item 7 (Maintenance) of this manual.
- The central vacuum plant should be considered as "Contaminated Medical Waste" after its service life is completed.
- The user is responsible for creating a safe working environment. If some parts and accessories are considered to interfere with a safe working environment, they should be replaced immediately.
- The maintenance and operating instructions of the central vacuum plant must be followed exactly. Maintenance should be done in a timely manner with suitable materials.
- Installation, operation, repair and maintenance should only be carried out by authorized and trained personnel.
- The rooms where the switchboards are located must be locked, and unauthorized persons must be prevented from entering the rooms.
- The room / rooms where the central vacuum plant is located must be clean and kept away from flammable and caustic gases. The room (s) should be protected against flooding.

- The room / rooms where the central vacuum plant is located must be clean and kept away from flammable and caustic gases. The room (s) should be protected against flooding.
- The device contains high voltage and moving mechanical parts. It can cause permanent and fatal accidents in the interventions of unauthorized and untrained people.
- Pipe connection diameters should be chosen correctly and medical copper pipes suitable for the intended use should be used.
- Ensure that all phases are correct and complete by making proper electricity supply.
- ÜZÜMCÜ R&D department reserves the right to change and / or remove the technical specifications of Central Vacuum Plants and their equipment and the information contained in this manual.

3.1. EXPLANATIONS OF SYMBOLS VIEWED ON VACUUM PUMP

Wear ear protection

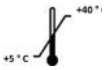
Follow the instructions for use.

Check guards and safety devices

Attention! Dangerous voltage

Caution! Do not touch hot surfaces (risk of burns)

Warning: Automatic start



Working Environment temperature

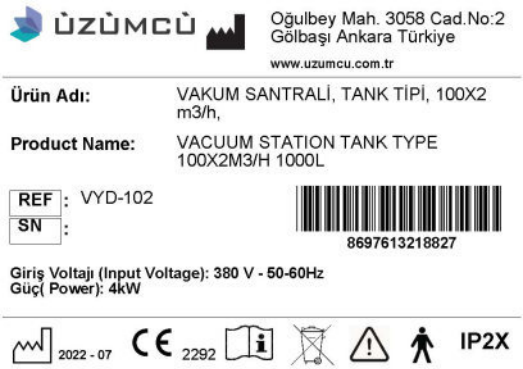
Warning: Evacuation of hot or dangerous gases

3.2. SYMBOLS AND EXPLANATIONS

Symbol	Explanation	Symbol	Explanation
	Follow the instructions for use.		Catalog Number
	Consult the instructions for use.		Serial Number
	Attention: Consult accompanying documents		Compliant with MDD 93/42 / EEC Medical Devices Directive
	Production date	2292	Notified Body Number
	Producer		Environment Humidity
	Alternative current		Ambient temperature
	Dangerous Voltage		Fragile, handle with care
	Protective Grounding		Protect from sunlight
	The enclosure can only be opened by trained service personnel.		Keep Dry
	B Type Device		Keep it upright
	Recycling: Electronic Equipment		Do not use hooks
	General Warning Sign,		Do not carry by holding here.
	Follow the instructions for use.		Do not touch oil.

3.3 SAMPLE PROMOTION LABEL

Inner Label



External Label

> ⚠ ATTENTION!
> No changes should be made on the device label and the label should not be removed.

4.1 TRANSPORT AND STORAGE ENVIRONMENT

In Transport and Storage:

• Ambient temperature should be between 0 ° C and + 50 ° C.
• Humidity ratio should be between 30% and 70%.
• Atmospheric pressure should be between 0.49 atm and 1 atm.

4.2 STORAGE CONDITIONS

Central vacuum plants are shipped as packaged. After receiving the central vacuum plant;

- Carefully open the nylon package.
- Examine the device carefully and determine whether it is damaged during transportation. For your device damaged during transportation, please contact the relevant sales point.
- Central vacuum plants must be protected from moisture, rain and excessive heat during transportation and storage.
- Central vacuum plants should be transported carefully. It is a fragile product.
- Central vacuum plants should not be reversed.
- Keep the central vacuum plants in their own packaging.

⚠ ATTENTION!
In order for the system to work safely, the device must be fixed to the ground.

⚠ ATTENTION!
The water accumulated in the vacuum tank should be evacuated by opening the drain valve once a month.

4.3 TRANSPORT CONDITIONS

Central vacuum plants must be transported on pallets.

5.1. DEVICE OVERVIEW

- Central vacuum plants are systems consisting of pumps, tanks and other equipment to meet the vacuum needs of the hospital.
- ÜZÜMCÜ brand central vacuum plants are designed for the production and storage of vacuum to be used in hospitals. The capacity is determined according to the bed capacity of the hospital where the plant will be used.
- The facility should be installed in a well ventilated environment. This prevents the pumps from overheating and decreasing their efficiency.
- At least two pumps are used in the systems for operational safety.
- The power plant is fully automatic. When vacuum is used in the plant, the vacuum sensors sense the pressure increase and the selected pump is automatically activated, the desired vacuum level is provided and automatically deactivated.
- It is designed to provide the vacuum needed by hospitals and laboratories.
- PLC control is a fully automatic system.
- Bacterial filters are used in the power plants.
- Air-cooled, oil-type vacuum pumps are used in the power plants.
- Thanks to the sliding shelves used in bunk-type vacuum plants, it is possible to reach the motors easily.

5.2. INTENDED USE AND AREAS OF USE

Intended Use

- Central vacuum plants generate vacuum in order to meet the central vacuum requirement in medical gas facilities. Vacuum plants, hospitals, laboratories, clinics, etc. used in facilities.

Target User

- Central vacuum plants are used by hospital technical staff.

Side Effect

- If the user manual is followed, the device does not have a defined side effect.

Target Poppulation

- It can be used in any patient where vacuum is required. There is no restriction.

Indications

Central vacuum power plants are used in the treatment and alleviation of the disease. It is intended to support treatment.

- Cleansing the airways of blood, saliva, vomiting or other secretions so that a patient can breathe.
- To prevent pulmonary aspiration that can lead to lung infections, Cooling, opening of airways
- To facilitate breathing and prevent the growth of microorganisms,
- To view the surgeon and to remove blood from the operated area to allow the study.
- After an intracranial hemorrhage, a vacuum can be used to remove blood that has accumulated in the skull.
- It can also be used in gynecology;
- Used for expressing milk in newborn units.
- Used in childbirth and abortion when vacuum support is needed.

Contraindications

- Fetal prematurity (<34 weeks of gestation)
- Fetal scalp trauma attached head
- Incomplete cervical dilatation
- Active bleeding or suspected fetal coagulation defects
- Suspected macrosomia
- Off-the-corner presentation or other false statements
- Cephalopelvic disproportion
- Inadequate anesthesia

Organs in Contact with the Device
The device does not have any contact with the patient, healthcare personnel or doctor. There is only contact with the authorized technical service personnel of the hospital during installation, maintenance and cleaning.

Usage Time / Body Contact Time
Vacuum plants do not come into contact with the body. /
There is no time limit for contact with the body.

Disposable / Reusable Condition
Central vacuum plants are multi-use devices.

Sterilization
Central vacuum plants are not sterile products.

Invasiveness
Central vacuum plants are non-invasive.

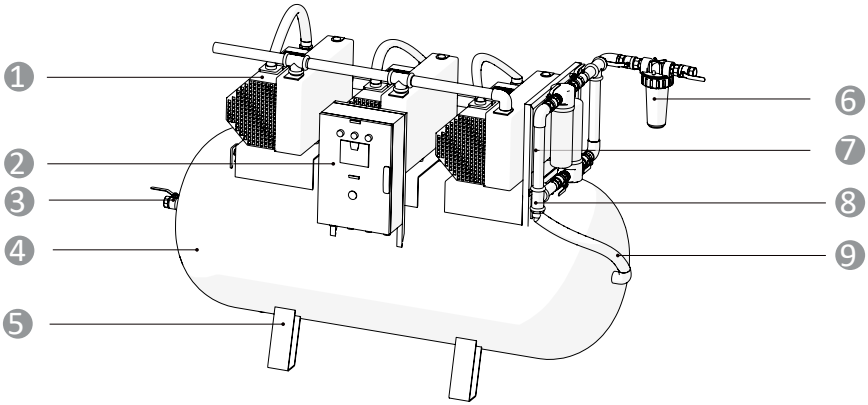
Shelf life
Central vacuum plants do not have a shelf life. The product life is 10 years.

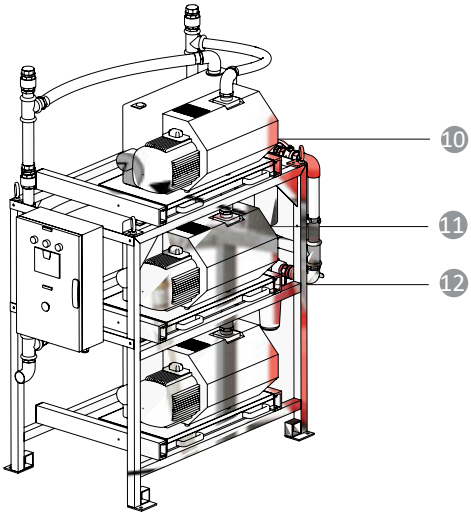
Conditions to Avoid
It should not be used in flammable, flammable environments and environments where evacuation is inadequate.

5.3.DEVICE AND PARTS DEFINITIONS

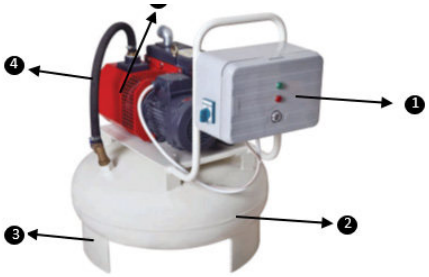
PART NO	PART NAME
1	PUMO
2	PLCCONTROL PANEL
3	BCONNECTION VALVE
4	TANK
5	TANK LEGS
6	EMERGENCY STOP BUTTON
7	VACUUM PIPE
8	EXHAUST PIPE

PART NO	PART NAME
1	PUMP
2	CARRY RING
3	PLC CONTROL PANEL
4	EMERGENCY STOP BUTTON
5	SLIDING RAIL SYSTEM
6	VACUUM PIPE
7	OPEN-CLOSE VALVE
8	EXHAUST PIPE

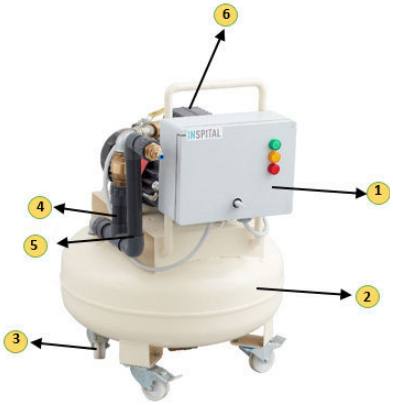




PART NO	PART NAME	PART NO	PART NAME
1	VACUUM PUMP	7	BACTERIA FILTER
2	PLC CONTROL PANEL	8	VACUUM LINE
3	CONNECTION VALVE	9	PIPE CONNECTION
4	TANK	10	CARRYING RING
5	TANK LEGS	11	BUNK
6	WATER HOLDING FILTER	12	SLIDING RAIL SYSTEM

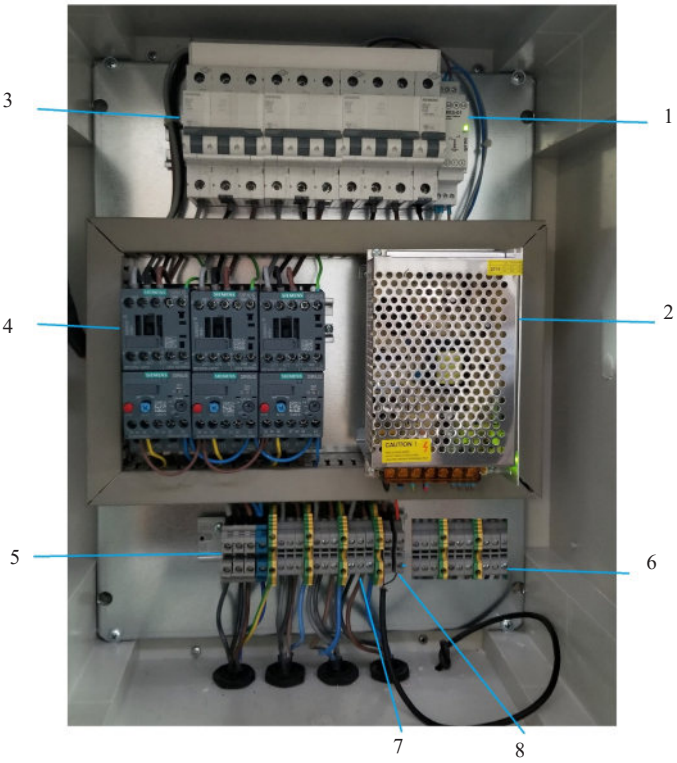


PART NO	PART NAME
1	CONTROL PANEL
2	MİNİ VACUUM TANK
3	MINI VACUUM TANK FOOT
4	VACUUM HOSE
5	PUMP



PART NO	PART NAME
1	CONTROL PANEL
2	MINI VACUUM TANK
3	MINI VACUUM TANK WHEEL
4	EXHAUST PIPE
5	VACUUM PIPE
6	PUMP

PLC Inside of Board



PART NO	PART NAME
1	Motor Koruma Rölesi
2	AC / DC Converter (PLC Power Supply)
3	Protection Fuse (3x10A Ctype)
4	Softstarter - Contactor
5	Phase input
6	Operating Room AGSS Terminal output connections
7	Motor connection outputs
8	Sensor Connection Output

Vacuum Pumps: Approximately -0.8 to -0.9 atm. It is a vacuum generator that can create negative pressure and constitute a source for the vacuum installation. With its special electrical control panel, it operates automatically or manually when vacuum is needed in the system, and automatically stops when sufficient vacuum is provided. The system should consist of at least 2 or 3 pumps. Pumps are integrated with the oil cooler fan system. The fan mounted on the motor - pump shaft ensures cooling of the oil passing through the oil cooler. Thanks to this system, the performance of the pump has been increased. Since the pumps are cooled by the air in their environment, it should be ensured that the ambient temperature is in normal conditions. The air sucked by the vacuum pump is thrown out of the environment with an exhaust pipe of appropriate diameter, without creating an air flow towards the living units.

Control Panel (PLC): In harmony with the vacuum pumps in the vacuum plant makes it work.
Thanks to the vacuum sensors used in the system,
It automatically ensures the operation of the vacuum pump and the stopping of the vacuum pump when sufficient vacuum is reached.
Control panel allows to manage vacuum pumps.
Sets the vacuum values as lower limit and upper limit.
Gives warning when oil maintenance is required.
Provides failure reporting.
Emergency stop button cancels all operation in adverse condition

Vacuum Tank : It has an internal volume to store the vacuum produced by the vacuum pump, -0.9 atm. It is a cylindrical tank made of pressure resistant material. It has a drain plug for cleaning, feet that fit firmly on the floor and can be fixed. It is insulated against corrosion. Its capacity is determined by the institution. At least 1 or 2 vacuum tanks are installed in the system.
The outer casing of the vacuum tank is made of steel sheet. Electrostatic for corrosion resistance Painted with teak powder paint. The tank volume is determined by calculating the vacuum usage capacity of the hospital. Warehouses can be in a horizontal or vertical position depending on their usage capacity.r.

Filter Group: Unwanted particles, dust and dirt in the central medical vacuum installation-
It is the filter that prevents it from escaping to the vacuum pump. Two by-pass line filters
It is formed by connecting with conical fittings. System 150 m3 / h capacity, one pre-holder and the other
With two filters, one of which is antibacterial, which is capable of holding micro-organisms. occurs.
The occupancy rates of the filters can be followed by the indicators on them.

Drain Valve: It is installed under the vacuum tank. Manually at certain times
allows the dewatering inside the vacuum tank to be evacuated by opening

5.4. SPARE PARTS

PLC CONTROL PANEL

- It enables the vacuum pumps in the vacuum plant to work in harmony.
- With the vacuum gauge inside, it automatically enables the vacuum pump to work when the vacuum value in the system decreases, and the vacuum pump to stop when sufficient vacuum is reached.
- Control panel allows to manage vacuum pumps.
- Vacuum values are set as lower limit and upper limit.
- Gives warning when oil maintenance is required.
- Provides failure reporting.
- Emergency stop button cancels all operation in adverse situations.
- ÜZÜMCÜ PLC panels are fully automatic and digital control units.
- It is designed to control more than one central vacuum pump in vacuum stations.
- Provides equal aging of pumps and longer service life for vacuum.

BACTERIA FILTER SET

- 100 m³ / h flow capacity
- Integrated bypass valves and discharge system
- 30 micron bacteria filtration

LIQUID HOLDER

MODELNO
VK40.28

VACUUM TANK

MODELNO	WALL THICKNESS (MM)	DIAMETER (MM)	CAPACITY (L)	LENGT (MM)
3350.05	5	630	500	1800
3350.75	5	750	750	1800
3350.10	6	850	1000	1920
3350.15	6	1100	1500	2200

VACUUM PUMP

- Specially designed for medical applications.
- Stable and long life
- It has high pumping speed even at low pressure.
- It is single stage.
- Pumps can run continuously from atmospheric pressure to final vacuum
- There is an integrated oil mist filter in the exhaust.
- Oil level button and PT100 temperature sensor options are available.
- It is silent and robust.

5.5. TECHNICIAL SPECIFICATIONS

5.5.1. Tank Type Central Vacuum Station

Model No	VYD-42	VYD-43	VYD-102	VYD-103	VYD-202	VYD-203
System Capacity (m3/h (50hz)	47x2	47x2	100x2	100x3	200x2	200x3
Power (kW) (50 Hz)	2	2	2	2	2	2
Punp Number (Unit)	2+1	3	2+1	3	2+1	3
Tank Capacity (L)	500	500	1000	1000	1000	1000
Number of Bactarial Filter	1	1	1	2	2	2
Number of Water Trap Filter	1	1	1	1	1	1
PLC Number	1	1	1	1	1	1
Inlet Hose Diameter	1”	1”	1”1/4	1”1/4	2”	2”
Outlet Hose Diameter	1”	1”	1”1/2	1”1/2	2”	2”
Bed Capacity	70	50-90	90-180	150-200	160-300	160-350
Width x Length x Height(mm)	1120x2100x1500	1120x2100x1500	1120x2100x1500	1120x2100x1500	1120x2100x1500	1120x2100x1500
Voltage Level	380 V	380 V	380 V	380 V	380 V	380 V
Nominal Current Level	6A	6A	6A	6A	6A	6A
Number of Phase	Three Phase	Three Phase	Three Phase	Three Phase	Three Phase	Three Phase
Grounding Type	ExternalandInternal Grounding	Externaland InternalGrounding	Externaland InternalGrounding	Externaland InternalGrounding	Externaland InternalGrounding	ExternalandInternal Grounding
Insulation Class	Class I	Class I	Class I	Class I	Class I	Class I
Insulation Type	B	B	B	B	B	B
Software Information	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01
Compliance with Electrical Standards	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008
Fuse Information	63 A, C Type	63 A, C Type	63 A, C Type	63 A, C Type	63 A, C Type	63 A, C Type

5.5.2. Vertical Type Cental Vacuum Station

Model No	VRD-42	VRT-43	VRD-102	VRT-103	VRD-202	VRT-203
System Capacity (m3/h) (50 hz)	47x2	47x3	100x2	100x3	200x2	200x3
Power (kW) (50 Hz)	2	2	2	2	2	2
Pump Number (Unit)	2+1	3	2+1	3	2+1	3
Tank Capacity (L)	500	500	1000	1000	1500	1500
Number of Bacterial Filter	1	1	1	2	2	2
Number of Water Trap Filter	1	1	1	1	1	2
Inlet Hose Diameter	1”	1”	1”1/4	1”1/4	2”	2”
Outlet Hose Diameter	1”	1”	1”1/2	1”1/2	2”	2”
Bed Capacity	70	50-90	90-180	150-200	160-300	160-350
Width x Length x Height(mm)	700x1150x1850	700x1150x1850	700x1150x1850	700x1150x1850	700x1150x1850	700x1150x1850
Voltage Level	380 V	380 V	380 V	380 V	380 V	380 V
Nominal Current Level	6A	6A	6A	6A	6A	6A
Number of Phase	Three Phase	Three Phase	Three Phase	Three Phase	Three Phase	Three Phase
Grounding Type	ExternalandInternal Grounding	ExternalandInternal Grounding	ExternalandInternal Grounding	Externaland InternalGrounding	Externaland InternalGrounding	ExternalandInternal Grounding
Insulation Class	Class I	Class I	Class I	Class I	Class I	Class I
Insulation Type	B	B	B	B	B	B
Software Information	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01
Compliance with Electrical Standards	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008
Fuse Information	63 A, C Type	63 A, C Type	63 A, C Type	63 A, C Type	63 A, C Type	63 A, C Type

In tank-type central vacuum plants, in addition to 2 pumps, a third vacuum pump that is inactive in accordance with the ISO 7396-1 standard is supplied to the consumer. The pump, whose connections are ready, is directly activated in case of failure of one of the active pumps.

5.5.3. Mini Vacuum Plant

Model No	AGM-00	AGM-01
Sistem Capacity (m3/h) (50 hz)	28	2x10
Power (kW) (50 Hz)	2	2
Pump Number (Unit)	1	2
Tank Capacity (L)	70	70
Noise Level dB (A)	60	60
Inlet Hose Diameter	1”1/4	1”1/4
Outlet Hose Diameter	1”1/4	1”1/4
Width x Length x Height (mm)	980x870x650	980x870x650
Voltage Level	380 V	380 V
Nominal Current Level	6A	6A
Number of Phase	Three Phase	Three Phase
Grounding Type	External and Internal Grounding	External and Internal Grounding
Insulation Class	Class I	Class I
Insulation Type	B	B
Software Information	U90 Ladder software version 15.01.01	U90 Ladder software version 15.01.01
Compliance with Electrical Standards	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008	60601-1:2009, 60601-1-2:2016, 60601-1-8:2008
Fuse Information	63 A, C Type	63 A, C Type

5.5.4. Vacuum Pumps

Model No	Nominal Flow		Rotation Speed		Noise Level	Oil Capacity	Weight
	$m^3.h^{-1}$		Rpm				
	50 Hz	60 Hz	50 Hz	60 Hz	db (A)	l	kg
VPS-25	28	33	1435	1690	60	1,5	30
VPS-40	47	53	1430	1715	62	1	34.3
VPS-70	68	81.6	1420	1705	64	3	63.4
VPS-100	100	120	1440	1730	65	3	67.2
VPS-150	132	156	970	1150	66	5	154
VPS-200	200	240	1455	1765	67	5	143
VPS-300	300	360	1450	1740	69	5	172

6.1 SETUP

6.1.1. Pre-Installation Media Preparation

The pre-installation preparation steps outlined below are the same for all vacuum unit models mentioned in this manual:

The connection of the vacuum pump with the chamber or system to be vacuumed should be made with pipes of the same size as the pump inlet. Tubes with very long or small diameters will cause a decrease in pump performance. The weight of the pipes and fittings should not be put on the pump. It is recommended for the convenience of the connection between the pump and the pipeline with flexible vacuum hose. The tightness of all joints prevents leaks that may occur in the system.

Since your vacuum pump is designed to operate without vibration, it does not need to be fixed to the ground. However, in cases where the pump needs to be fixed (such as mounting inside the machine), the connection holes under the pump vibration mounts should be used.

The switchboard must be brought to the desired area to be installed and must be placed on its feet horizontally, balanced and fixed. The area where the plant will be installed should be a flat and concrete floor.

Place your pump in a private area accessible to qualified personnel. Place it on a flat surface on vibration pads. It must be accessible for easy and accurate maintenance. Provide adequate air circulation in the area where the pump is placed. Avoid contact of the pump with water. When the pump is mounted outside, it should be protected from atmospheric effects and the pump oil recommended in the service manual should be used.

It is possible to give the pump exhaust outlet to another desired place or outside with pipes. This outlet should be given directly to the atmosphere in case of explosion caused by oxygen. In order to prevent living creatures from entering the pump exhaust, a cage should be placed at the exhaust outlet. Pipes of the same size as the pump exhaust outlet should be used. For longer pipelines, larger pipes should be used and the weight of the pipe should not be on the pump. The line must have a downward slope so that the oil condensed in the pipeline does not return. Elbows should not be used in the pipeline.

1m of intervention and ventilation space should be left around the plant.

All electrical connections of the pump must be made by qualified personnel in accordance with the regulations in force where the pump is used.

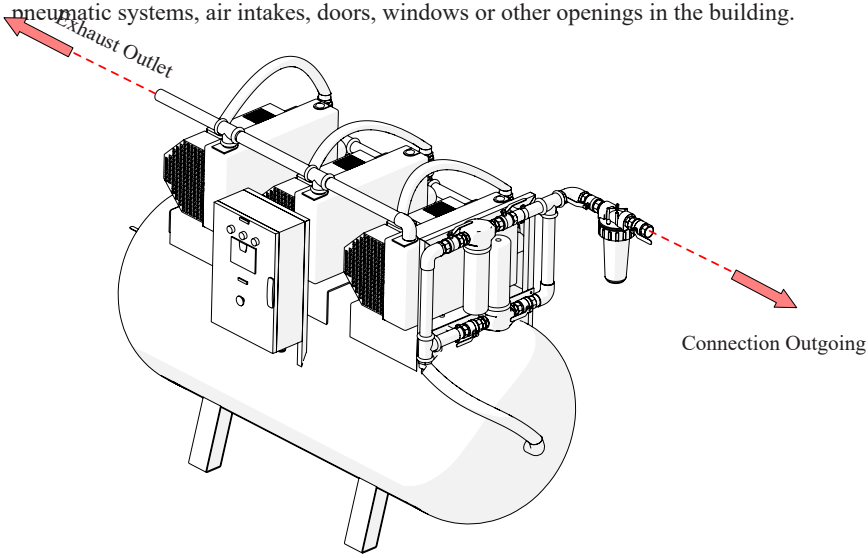
All electrical equipment used EN 60601-1-2 electromagnetic compatibility must comply with the directives. Check that the operating voltage matches the voltage and frequency values on the motor nameplate. The electric motor must be protected against overload. Ampere values on the motor nameplate should be considered as reference. It must be ensured that the electricity network to which the vacuum plant is connected is grounded. The electrical connection is made in accordance with the diagram in the service manual. In case the pump rotates in the opposite direction, the cables of two of the three phase cables should be changed to ensure that the pump rotates in the correct direction.

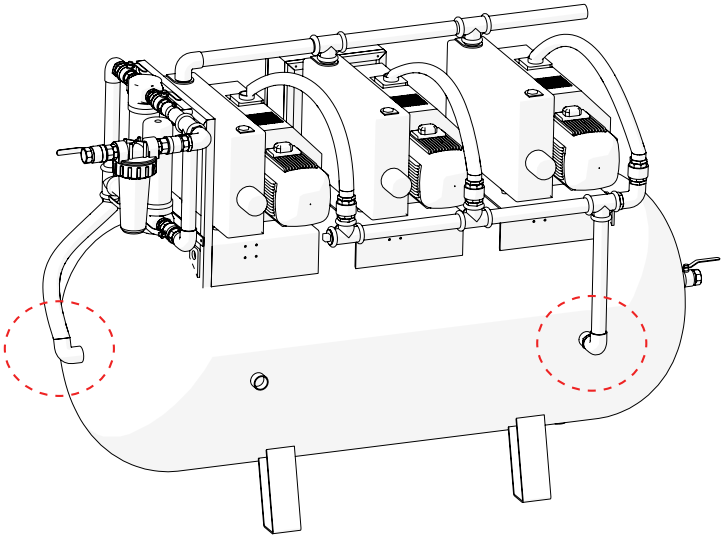
6.1.2. Setup

- The connection and installation of the power plant is carried out by UZUMCU Tıbbi Cihaz ve Medikal Gaz Sistemleri A.Ş or authorized service, this must be notified by the buyer company during the order. Otherwise, ÜZÜMCÜ Medikal Teknoloji A.Ş. or authorized service is not responsible for the connection and assembly of the device.
- Installation of the switchboard should only be carried out by an authorized service or hospital technical personnel trained by ÜZÜMCÜ authorized service.

Tank Type Central Vacuum Plant Installation

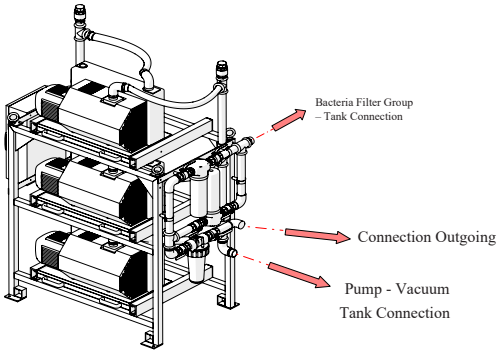
- The vacuum plant should be brought to the desired area to be installed. The floor of the area must be a flat concrete floor.
- After the position of the unit is adjusted, the unit should be fixed to the ground. This fixing should be carried out by our authorized technical service and installation personnel.
- The connection of the bacteria filter group, pump suction outlets to the tank should be made and the connection to the installation should be made.
- The exhaust outlet must be connected to the ventilation system.
- After the exhaust outlet connections are made, electrical connection must be made with the cables coming from the control panel.
- Attention should be paid to the proper ventilation of the area where the plant is located.
- The exhaust line of the plant should be connected to the atmosphere, and the vacuum line to the installation through medical copper pipes. Exhaust line and vacuum blown, this user manual “5.3. Device and Part Definitions ”is shown in the heading line.
- For the location of the exhaust outlet, the possible effects of the existing wind should be taken into account.
- The location of the exhaust outlet; It should be away from the air intake of medical pneumatic systems, air intakes, doors, windows or other openings in the building.



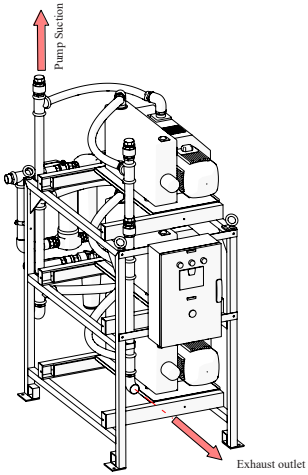


Vertical Type Central Vacuum Plant Installation

- The vacuum plant should be brought to the desired area to be installed. The floor of the area must be a flat concrete floor.
- After the position of the unit is adjusted, the unit should be fixed to the ground. This fixing should be carried out by our authorized technical service and installation personnel.
- The connection of the bacteria filter group, pump suction outlets to the tank should be made and the connection to the installation should be made.
- The exhaust outlet must be connected to the ventilation system.
- After the exhaust outlet connections are made, electrical connection must be made with the cables coming from the control panel.
- Attention should be paid to the proper ventilation of the area where the plant is located.
- The exhaust line of the plant should be connected to the atmosphere, and the vacuum line to the installation through medical copper pipes. Exhaust line and vacuum blown, this user manual “5.3. Device and Part Definitions ”is shown in the heading line.
- For the location of the exhaust outlet, the possible effects of the existing wind should be taken into account.
- The location of the exhaust outlet; It should be away from the air intake of medical pneumatic systems, air intakes, doors, windows or other openings in the building.



Connect the exhaust outlet to the ventilation system, then make the electrical connection with the cables coming from the control panel.



⚠ ATTENTION!
Post-installation tests comply with TS EN 7396-1: 2016 standard, make the test- yeast authorized persons (manufacturer, hospital biomedical unit and machine engineers).

Mini Vacuum Plant Installation

- The vacuum plant should be brought to the desired area to be installed. The floor of the area must be a flat concrete floor.
- The connection of the bacteria filter group, pump suction outlets to the tank should be made and the connection to the installation should be made.
- The exhaust outlet must be connected to the ventilation system.
- After the exhaust outlet connections are made, electrical connection must be made with the cables coming from the control panel.
- Attention should be paid to the proper ventilation of the area where the plant is located.
- The exhaust line of the plant should be connected to the atmosphere, and the vacuum line to the installation through medical copper pipes. Exhaust line and vacuum blown, this user manual “5.3. Device and Part Definitions ”is shown in the heading line.
- For the location of the exhaust outlet, the possible effects of the existing wind should be taken into account.
- The location of the exhaust outlet; It should be away from the air intake of medical pneumatic systems, air intakes, doors, windows or other openings in the building.

6.1.3.Information to be Considered in Installation

For all materials used in the installation, including pipes and fittings, terminal units and the like, the manufacturer must comply with TS EN ISO 9001: 2015 standards.

Pipeline components that are likely to come into contact with real gas must meet the requirements of EN 13348 and ISO 15001 Cleaning as applicable, and service ducts or voids containing pipelines that favor contamination and the like before and during installation must have adequate ventilation to prevent gas formation in the event of any leakage. .

In other locations where pipelines are favored (and pressure tested) along their entire length, ventilation is not required.

Open flowing pipelines should not be installed in elevator shafts, kitchens, laundries, boilers, generator rooms, combustion rooms, storage rooms designed to accommodate flammable materials, or other fire risk areas.

Where pipelines in hazardous areas are unavoidable, they should be sealed with non-combustible, non-corrosive materials that do not have an electrolytic reaction with copper to avoid the possibility of gases being released into the room in case of pipeline failure.

Medical gas pipelines should be routed away from natural gas pipelines where a gas mixture has the potential to accumulate in the event of a leak.

When operating in closed channels with other services such as pipelines, steam main lines and water supply systems, they should be checked regularly as corrosion may occur as a result of chloride deposits following leakage. It should not be operated in closed channels with other services over which they cannot be controlled.

External piping should be avoided whenever possible. However, when external work is required, they should be protected as follows:

a. On external vertical surfaces up to the maximum exposure height possible to damage (eg vehicle movement): by means of galvanized, profile section steel of sufficient thickness to ensure adequate protection.
The protection should cover the entire area covered by the pipelines, but stay away from the surface so that the pipes can be visually inspected (the armor should be easily removable to allow for more detailed inspection);
b. horizontal surfaces, roofs, etc. when passing: a protection similar to (a) above should be provided to withstand "stepping" damage using the profiled section as above. The materials used for the pipes must be made of non-arsenic copper, deoxygenated with phosphorus..

ATTENTION!

In order for the pressure level alarms of the Vacuum Plant to be audible by the user, the vacuum line must be connected to the gas control box that gives an audible alarm.

Copper Quality Used
- BS EN 13348: 2001 - R250 (semi-rigid) for sizes up to 54 mm; or
- BS EN 13348: 2001 - R220 (annealed) for larger dimensions

Pipe fittings should be end-fed capillary fittings according to BS EN 1254-1: 1998.
Extended connections can be used for straight couplings.

Other fittings for connection to copper pipes (eg valve and control panel fittings) can be copper, brass, gun metal, bronze or stainless steel.

All pipes for oxygen service must be cleaned and degreased and free of particulate matter and toxic residues in accordance with BS EN13348: 2001.

Bottom of all pipe fittings and fittings for connection to pipes
their assemblies must be cleaned and degreased for oxygen service and must be free of particles and toxic residues.

It must be individually sealed in bags or boxes and delivered to the site defined as medical gas fittings.

Although vacuum installations are not required to be degreased, they are often installed by the contractor simultaneously with medical gas pipelines. Therefore, degreased pipes and fittings should be used in vacuum installations to prevent confusion. PVC piping can also be used for vacuum and AGSS, but is unlikely to benefit other than exhaust discharges.

Pipes should only be cut with impeller pipe cutters, not with hacksaws, to prevent copper particles from entering.

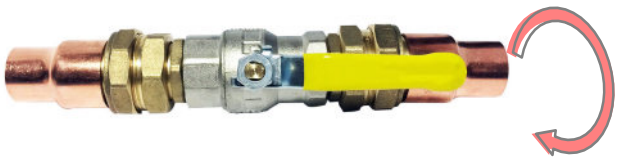
6.2. USAGE

6.2.1. Working principle

In central vacuum plants, negative pressure is created with the help of vacuum pumps. This pressure is collected in the vacuum tank. The purpose of generating negative pressure in the vacuum tank is to create a homogeneous and measurable pressure.
The suction part of the vacuum plants is connected to the gas network of the hospitals. Before the system is connected to the network, a water trap and bacteria filter must be installed in the tank.
Anti-bacteria filter prevents bacteria and harmful substances from entering the tank. The water retaining filter, on the other hand, holds the aspiration residues escaping to the system and prevents these wastes from entering the tank.
The capacity of the vacuum tank to be used is determined according to the needs of the hospital.
The working principle of vacuum pumps is that the pallets on the rotor rotating with centrifugal force sweep the stator and create a vacuum by lubricating the inside. The capacity of the vacuum pump is determined as a result of the calculations made in line with the needs of the hospital.
Damage to the system as a result of current and pressure changes that may occur in the electrical control panel is prevented. The electric control panel has the feature of starting the pumps automatically.
Thanks to the digital indicator on the panel, the operation and fault information of the pumps can be seen easily.

Location of Valves

The opening-closing is open in the position shown below. When turned in the direction of the arrow, the valve is closed.



6.2.2. WORK ENVIRONMENT

- Working environment temperature should be between + 5 ° C and + 40 ° C.
- Plants should be kept in a safe, sheltered and clean environment.
- The plants should be positioned on flat and concrete floors.
- While placing vacuum plants, potential hazards such as contamination and fire arising from the locations of other equipment and other supply systems in the same room should be taken into consideration. These places should be designed with unloading vehicles in mind.
- Plants should not come into contact with oil.
- There should not be any flammable explosive materials around. It should not be used with the oxygen tank. If an oxygen tank is used in its vicinity, this place should be at a sufficient distance from the buildings by taking the necessary safety measures. Attention should be paid to the proper ventilation of these spaces.
- Safety valve and discharge valve outlets will be opened to the atmosphere outside the building with a pipe of sufficient diameter, and a sign written "Attention, Keep Clean, Medical Gas Discharge Point" will be placed at this point.
- The tubes to be used with the power plants should not be affected by any impact, vibration, etc. in such cases, they must be fixed with tube fixings in order not to fall and damage the system. There should be chain links on the tube fixers to fix each tube separately. There will be one discharge valve for each cylinder group in the system.

6.3. PLC CONTROL PANEL INTRODUCTION AND USE

6.3.1. PLC CONTROL PANEL INTRODUCTION

- It has a colorful and easy-to-use screen.
- It has an adjustable working system up to 3 pumps.
- Panel can be operated with keys.
- The system works automatically.
- Equal aging working system is available to extend the life of the pumps.
- Pump temperature can be set as dry contact.
- Pressure measurement units can be selected in the settings menu and selected in mmHg.
- Pump transition times are factory set. However, transition times can be adjusted according to the tank capacity needed by the hospital. (When a pump is running, if the running pump cannot meet the required capacity, the backup pump is activated.)
- The start-stop values of the pumps can be adjusted.
- Central pressure values are displayed on the screen.
- Specially designed for medical applications.
  Stable and long-lasting
- It has high pumping speed even at low pressure.
- It is single stage.
- Pumps can run continuously from atmospheric pressure to final vacuum.
- There is an integrated oil mist filter in the exhaust.

- Oil level button and PT100 temperature sensor options are available.
- It is silent and robust.
- Energy and thermal failures of the pumps are displayed on the screen.
- Pump running hours are displayed and recorded on the screen.
- The interface of the control panel can be set up in Turkish or English according to the user's request. This setting is made by the ÜZÜMCÜ Authorized Technical Service at the first installation.
- User login is provided with a password system to change the default settings.

6.3.2. PLC KUSE OF ONTROL PANEL

System status and warning information can be viewed on the PLC panel of the Central Vacuum Station. The user can use the PLC panel to turn the device on and off. Use the "0" button for switching on and off.
When you see any warning on the screen, ÜZÜMCÜ call the authorized service. In order to eliminate the warnings, authorized technical service or technical personnel trained by İnspital A.Ş can intervene in the device according to SM.01 SM.02 service manuals.

KEY VISUAL	EXPLANATION
	Arrow keys
	Information key with PLC related information
	Enter key
	Keypad is used only by authorized service.

- When the device is turned on for the first time, the "ÜZÜMCÜ" screen appears on the screen.
- The system will not work unless upper and lower limits are defined in the system.
- Lower - upper limits are defined by the manufacturer and delivered ready to the user.
- The zero key "0" is the system power key

When the device starts up, the status information "system armed" appears. When the system is active, the green light on the panel turns on.

When the device stops, "system stopped" information appears.

7.1. CLEANING

If the vacuum pump needs to be cleaned, use a soap solution with a clean cloth.. Never use abrasive materials. Keep acid and derivatives away from the device and pipes. Before cleaning, turn off the device at the main switch. In order to prevent the device from being activated during cleaning, a warning sign stating that the cleaning has been carried out should be hung on the switch.

Wipe thoroughly with a dry cloth.

Frequency: As required In order to clean the dust, external particles and unwanted parts formed in the vacuum tank, the valve at the bottom of the tank should be opened and unwanted substances in the tank should be removed. Oil change and periodic maintenance of the pumps can be done on time by following the time counter.. Filters should be checked at least once a month according to the use of the device. Dirty filters should be replaced with new ones.

⚠ ATTENTION!
Do not use abrasive products. Keep acids and derivatives away from the device and pipes.

7.2. ALARM AND CALIBRATION

There is no manual pressure measurement device in the Central Plants. The measurement is provided by the sensor. Data is taken from the sensor. The measurement accuracy of the sensors should be checked and calibrated at least once a year. Sensors with deviations in the measured value must be replaced..

Fault alarm data were evaluated according to EN 60601-1-8 standards. Vacuum Plants provide 6 warning information to the user:

1. Emergency Stop
2. Check Thermal Waste
3. Sensor error broken or broken
4. Oil Change Time Is Over
5. Phase Sequence Error
6. Voltage Low

When one of these warnings is received, the actions to be taken and the responsibilities are examined under the heading "Possible Problems and Solutions".

1. Emergency Stop

It is activated when the Emergency Stop button is pressed. The system stops. As long as the Emergency Stop button is pressed, this warning will appear on the screen. When the emergency stop button is removed, the system armed notification appears on the screen..

2. Check Thermal Waste

If the phrase "Check thermal waste" appears, it indicates that one of the motors is out of order or one of the motor thermal waste is defective. However, it does not indicate which pump is faulty or which thermal waste is. When the warning is seen, in order to detect the complete failure, the personnel who are competent to intervene in the electrical panel must first open the panel and check which of the thermals is disabled. If there is any thermic failure, the information should be given when the service is contacted. If there is no one that is disabled, the problem is caused by the engine. The situation should be reported to the authorized service.

3. Sensor Error Broken or Broken

In case of failure in the connection of the sensor, in case of failure of the sensor, the warning of sensor error, broken or broken is given. Motors will not start until sensor failure is corrected.

4. Oil Change is Out of Time

When the oil maintenance time, which is determined by the manufacturer according to the characteristics of the system, "oil maintenance change time has expired" warning appears on the user interface. The alert will not disappear until the situation is corrected.

5. Phase Sequence Error

In case of incorrect connection of phases, “phase sequence failure” warning is given. It also causes the motors to run in reverse direction. The alert will not disappear until the situation is corrected.

6. Voltage Low

System gives low voltage warning in case of voltage line break or cut.

No data can be entered in the user settings.

7.3. MAINTENANCE

The vacuum sensor used in the system should be calibrated at least once a year. The device should be checked once a day to observe the operability of the general assembly and warnings.

ATTENTION!

Do not dismantle the pump more than necessary during maintenance, repair and service operations.

ATTENTION!

When performing maintenance and repair work, it is important to avoid risks associated with moving or live parts.
Before performing any service or maintenance on the pump:

- • The pump must be shut down and electrically interlocked.
  • Wait until the oil temperature drops to ambient temperature.
  • Isolate the pump without applying.

ATTENTION!

Depending on the application, parts and oil of the pump may be contaminated with substances absorbed by the pump. Apply appropriate safety regulations and use appropriate personal protective equipment.

ATTENTION!

These operations should be carried out by qualified and accredited personnel..

ATTENTION!

Failure to follow the manufacturer's recommendations and not using original parts during maintenance will result in invalidation of the warranty.

ATTENTION!

The dismantled rubber O ring or rubber flat seals must be replaced.

ATTENTION!

The bacterial filters of central vacuum plants should be changed in determined periods against the risk of contamination. Filters should be changed at least every 6 months.

ATTENTION!

Do not neglect to perform the maintenance of the engines within the specified periods. Otherwise, engine failure may occur.

ATTENTION!

The strength of the vacuum tank should be checked once a year. It is recommended that the check be carried out by a qualified person, preferably a mechanical engineer.
The system should be operated with negative pressure for half an hour in order to check the stability of the vacuum tanks. During this application, there should be no decrease in negative pressure. If there is a drop, contact the authorized INSPITAL technical service.

ATTENTION!

Maintenance and controls of the electrical panel should be done by the authorized service. The board must be locked at all times and the key must be accessible to technical personnel.
Keep the electrical panel away from moisture and water Otherwise, there may be a risk of electric shock.

ATTENTION!

It is the user's responsibility to use an oil other than the one recommended, and to interfere with the device other than technical service. Use of unsuitable or mixed oil can damage the pump. MIL'S oil safety data sheet can be provided on www.mils.fr website upon request.

ATTENTION!

Depending on the environment, the tank and panel should be dusted at least once a month.

7.3.1. PRECAUTIONS FOR VACUUM PUMPS

ATTENTION!

Full care must be taken to avoid any contact between oxygen and greasy parts (incompatible with oxygen).

ATTENTION!

During maintenance operations, all tools, spare parts, work area and hands must be degreased. Accessories, oil and greases must be compatible with oxygen.

7.3.2. OIL CHANGE

Check the oil level regularly. Perform the first oil change after the first 500 hours of use. The oil filter should also be changed at the first oil change. Technical Oil and filter change must be changed by ÜZÜMCÜ authorized service. The device will give a warning at the time of oil change. This period is 3000 hours. MIL's brand (MV99S) oil recommended by the manufacturer should be used for vacuum motors.

⚠ ATTENTION!

It is the user's responsibility to use an oil other than the one recommended, and to interfere with the device other than technical service. Use of unsuitable or mixed oil can damage the pump.

MIL'S oil safety data sheet can be provided on www.mils.fr website upon request.

⚠ ATTENTION!

To avoid the risk of spontaneous combustion or explosion, do not contact the vacuum line of the device with oil.

7.3.3. ELEKTRİK MOTORU

The maintenance of the electric motor should be done when the device warns about the oil change time. Oil change is routine maintenance for the electric motor, ie vacuum motor. Apart from this maintenance, the motors should be checked annually by the authorized technical service or by the authorized personnel who have received the maintenance training of the device. For detailed maintenance of vacuum motors, the instructions in the Service Manuals should be followed.

7.3.4. FILTER CHANGE

Filter selection should be made according to the flow rate of air passing through the system and the size of the connection.
The filter should be mounted in the direction of the arrow indicating the air flow direction on the filter.
There should never be any pressure in the system or in the air line before the filter is installed. Filters should be installed at a suitable distance from the compressor and various heat sources.

⚠ ATTENTION!

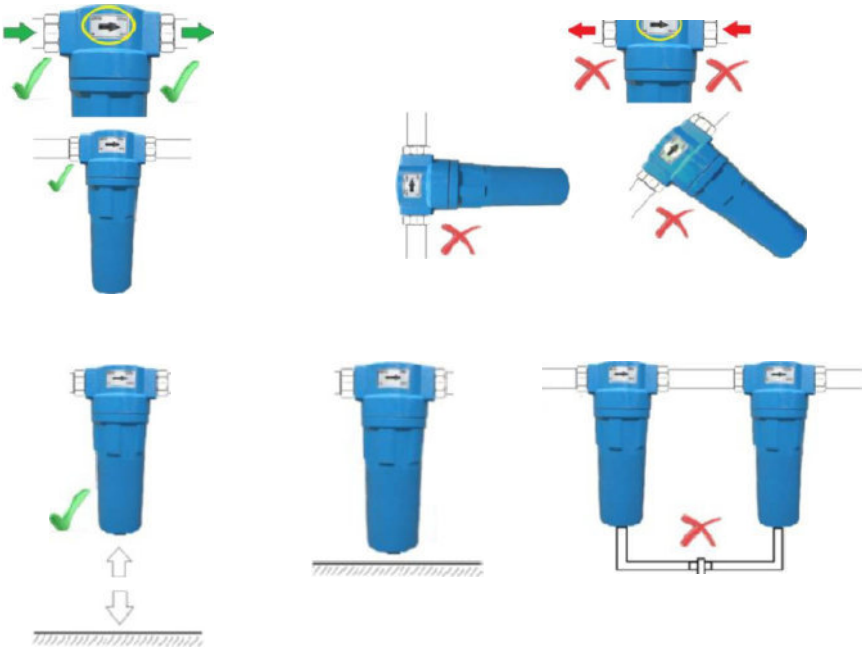
At the end of 3500 hours of operation or at the end of 12 months, the filter core must be replaced. Before replacement, the pressure in the filter must be relieved.

The drain valves of the filters (unless they are automatically drained) should be opened frequently and regularly, and the accumulated water and oil mixture should be discharged.

⚠ ATTENTION!
A safety valve should be installed in the compressed air line. The opening pressure of this safety valve should be selected according to the device or equipment with the lowest operating pressure in your system.

⚠ ATTENTION!
The opening pressure of the safety valve to be used for compressed air filters should be maximum 16 bar.

7.3.5 FILTER INSTALLATION



7.4 DISPOSAL OF WASTE

Before any disassembly, make sure that there is no risk from substances absorbed by the pump.
The pump should be disassembled. Materials must be sorted, collected and recycled in accordance with local and national safety and environmental regulations. The main wastes to be recycled are:

- Metallic materials
- DEEE
- Oil

Collection and retrieval must be carried out by approved service providers in accordance with the regulations in force in the country.

7.5 POSSIBLE FAULTS AND TROUBLESHOOTING

Please contact our authorized technical service for information about vacuum plant components and other information that may assist in the repair of vacuum plants. The tables given below describe possible malfunctions, causes and solutions.

Pump

Fault Description	Fault Cause and Possible Solutions	Responsible
1. The engine will not start.	1.1. Main power supply voltage of frequency incompatible with motor specification. 1.2. Check the circuit breaker setting. 1.3. Check the electrical connections. 1.4. Oil too sticky or room temperature too low. 1.5. Pressure increase in the exhaust unit: - Oil separation cartridge clogged - Pump exhaust line is blocked or blocked. 1.6. The hard point can be felt when the pump is turned by hand; check the wings.	1. Authorized technical staff 2. Authorized technical staff 3. Authorized technical staff 4. Authorized technical staff 6. Authorized technical staff
2. Pump flow rate is too low.	2.1. Pump not suitable for application. 2.2. The suction inlet strainer is clogged. 2.3. The suction filter (optional) is clogged. 2.4. Oil separation cartridge is clogged. 2.5. Too long pipe or diameter too small causing excessive head loss.	1. Authorized service 2. Authorized technical personnel and authorized service 3. Authorized technical personnel and authorized service 4. Authorized technical staffl 5. Authorized technical staff
3. Insufficient vacuum has been created.	3.1. Leaks in vacuum pipes or monitoring and control equipment. 3.2. Insufficient lubrication: add oil; or the filter is blocked. 3.3. The pump is too hot. 3.4. Air taken in in the holder (impurities, etc.).	1. Authorized technical staff 2. Authorized technical staff 3. Authorized technical staff 4. Authorized technical staff

Fault Description	Fault Cause and Possible Solutions	Responsible
4. The vacuum pump is overheating.	4.1. The room is too small, poorly ventilated or the room temperature is too high. 4.2. Insufficient distance between the wall and the pump fan. 4.3. Unsuitable oil. 4.4. The temperature of the sucked gas is too high. 4.5. The separation filter is starting to become clogged. 4.6. Exhaust line cross section is too small. 4.7. Insufficient lubrication: add oil or filter is clogged.	1. Authorized technical staff 2. Authorized technical staff 3. Authorized technical staff 4. Authorized technical staff 5. Authorized service 6. Authorized technical staff
5. The vacuum pump emits smoke in the exhaust or the oil consumption is high.	5.1. The separation cartridge is installed incorrectly. 5.2. The separation cartridge is broken or exploded. 5.3. Holder clogged or float filled with oil for reinjecting oil. 5.4. The oil filler cap is not tightened properly. 5.5. The vacuum pump is overheating. 5.6. Unsuitable oil.	1. Authorized technical staff 2. Authorized technical personnel, authorized service 3. Authorized technical personnel, authorized service 4. Authorized technical staff 5. Authorized service 6. Authorized technical staff
6. Oil is sucked into the vacuum chamber and backed up.	6.1. Non-return valve is defective. 6.2. Motor runs in reverse direction.	1. Authorized technical personnel, authorized service 2. Authorized technical personnel, authorized service
7. Abnormal sounds	7.1. The pump is making a clicking noise: the vanes are worn or deformed. 7.2. Metallic noises: the fan is touching another part or the cover is touching a lubricating tube. 7.3. Oil viscosity too high or oil too cold.	1. Authorized technical personnel, authorized service 2. Authorized technical personnel, authorized service 3. Authorized technical personnel, authorized service
8. Presence of water in oil	8.1. Pump sucks in fluids: catch liquids. 8.2. Install a gas ballast system. 8.3. The pump temperature is too low due to insufficient running time or the room is too cold: set up a preheating and rinsing system. Consult ÜZÜMCÜ for this. 8.4. Ducted exhaust and condensate returning to the pump: install a low point siphon.	1. Authorized technical personnel, authorized service 2. Authorized technical personnel, authorized service 3. Authorized technical personnel, authorized service 4. Authorized technical personnel, authorized service
9. The pump is not running	9.1. One of the stages may be faulty. Check the assembly and lines. 9.2. Pump may be stuck. 9.3. The engine may be faulty. 9.4. There may be a malfunction in the control panel elements.	1. Authorized technical personnel, authorized service 2. Authorized service 3. Authorized service 4. Authorized service
10. Suction power is low.	10.1. It may be time to fill in oil. Change the pump oil.	1. Authorized technical staff

PLC Control Panel

FAULT DETAIL	POSSIBLE CAUSE	SOLUTIONS	RESPONSIBLE
Low Voltage Warning in PLC Panel	Situations of rupture, disconnection in the tension line	Reconnection of the tension line	1. Authorized technical staff
Phase Sequence Error in PLC Board	Incorrect connection of phases	Phase connection must be corrected.	1. Authorized technical staff
Oil Change Time is Over warning on PLC Panel	When the oil maintenance time determined by the manufacturer according to the characteristics of the system comes up, the warning "oil maintenance change time has expired" appears on the user interface.	There is no oil change in Anesthetic Gas Evacuation Units. When you see this warning, reset the clock..	1. Authorized technical staff
Sensor Error, Broken or Broken warning appears on PLC Panel	In case of failure in the connection of the sensor, in case of failure of the sensor, the warning of sensor error, broken or broken is given.	Sensor connection should be checked.	1. Authorized technical staff
Thermal Waste Check warning appears on PLC Panel	The contactors to which the motors are connected are out of order The motor to which the contactor is connected does not work	The panel cover of the device should be opened by authorized personnel to check which thermal is disabled. If there is no thermal power that is disabled, the problem is caused by the engine. Call the authorized service.	1. Authorized technical staff
Emergency Stop warning appears on PLC Panel	The system stopped because the Emergency Stop button was pressed.	When the emergency stop button is removed, the system armed notification appears on the screen.	1. Authorized technical staff
Display screen on PLC Panel does not work.	1. Electricity supply problem 2. PLC Control Panel may be closed.	1. PLC Control Panel or external supply fuse may be defective or blown. Check the external supply electrical values. 2. Perform the operations in accordance with the PLC Control Panel Usage section of the User manual.	1. Authorized technical staff 2. Authorized technical staff
The switchboard does not work.	1. Electricity supply problem 2. PLC Control Panel may be closed.	1. PLC Control Panel or external supply fuse may be defective or blown. Check the external supply electrical values. 2. Perform the operations in accordance with the PLC Control Panel Usage section of the User manual.	1. Authorized technical staff 2. Authorized technical staff

8. RESPONSIBILITY MATRIX

Note: M for manufacturer, H for hospital.

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Supply Continuity	Complete or partial pipeline blockages	Drop or loss of supply to patient or devices	Flow and pressure test before using thermal units	Ü
	Loss of supply from supply source in operation	If the primary and secondary source fails, the system is supplied from a backup or emergency source.	Ensure that backup supply and emergency resources are added to the design in the supply system	H+M
			Ensuring that the capacity and locations of the spare and emergency sources of the supply system are added to the supply sources.	H
			Establishing a stock management system	H
			Taking maintenance measures in the installation of supply chains	H
			Determining the operation procedures of the roller rocks for emergencies	H
			Determining the minimum gas setup procedure in emergency situations	H
			Performing routine control of backup and emergency resources in case of problems in primary and secondary resources	H
			Routine control of alarm systems	H
			Determining operation management according to the operation management supply error	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Supply Continuity	Advanced pipeline damage	Total loss in heat units Loss of device and supply to patients	Pipeline design to reduce risk areas	H+M
			Designing the pipeline according to corrosion	M
			Designing the pipeline against mechanical damage	H+M
			Use of support to prevent corrosion that may occur in the pipeline	M
			In order to minimize electronic corrosion, the parts that are in direct contact with the pipeline	M
			Add grounding to prevent electronic corrosion	M
			Labeling to determine the direction of the pipeline flow	M
			Protecting the pipeline from critical areas	H
			Obtaining a work permit	H
			Adjusting the source or supply systems according to the usage areas of the location	H+M
			Emergency support procurement of areas with critical patients	H
			Use of emergency sources at adjacent points	H
			Use of emergency entry points close to emergency shut-off valves	H
			Performing routine alarm system testing	H
			Operation management document revealing the causes of the failure in the gas supply system	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Supply Continuity	Difficulties in gas supply due to external reasons	Late delivery of liquid or gas cylinders Supplier's products are not effectively stocked in cylinders or too small space	Selection of gas source in accordance with risk management principles	H
			Storage tank to be of appropriate size	H+M
			Using telemetry to storage tanks	H
			Adequate stock management and reordering systems are established	H
			Keeping a sufficient number of cylinders	H
			The areas where the cylinders will be located are smooth	H
			Training of personnel in changing the cylinders in the manifold system	H
			Emergency Plan	H
			Performing shipment planning and routine control	H
			Milk control of polan stock-resource stocks to be used in supply systems	H
			Operation management document revealing the causes of the failure in the gas supply system	H
	Late ordering of liquid or gas sources	Inadequate stocking method of health services.	Routine control of gas resources	H

Security Target	Root Cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Supply Continuity	Poor placement of resources	Mechanical damages cause losses in gas supply and supply sources are affected by sections close to each other.	To comply with local regulations in the allocation of supply sources	H+M
			Access to supply sources is difficult	H+M
			Mechanics causing an important source of supply	H
			Adequate physical security measures against mechanical damage	H+M
			Cleaning sign to keep gas production areas clean	H
			Procedures for accessing gas supplies	H
			Ensuring the system of routine control of gas supply places	H
			Checking the relationship between different zoned resources	H
Uninterrupted gas supply	Alarm malfunctions	Alarm condition not found	Adding UPS device for continuity of electricity supply	M
			To connect the alarms to the emergency power supply to keep the alarms in continuous operation.	H
			Observing the imaging signals coming from the alarm system	M
			Rütin alarm system test	H
			Rütin alarm system control and evaluation	H
			To be documented in the operation management document indicating the alarm failure	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Supply Continuity	Electrical Faults	Operational failure of electrical parts that may cause gas supply loss	Ensuring the electrical system of the UPS or emergency power supply for continuity	H
			Capacity control of the emergency electricity supply	H
			Performing routine electricity supply test	H
			Operation management document stating the supply of Electricity Supply	H
			Compliance with the procedure to ensure the parts to be used for power supply	H
			The problem with the electricity supply is that for the compressor or oxygen concentrators to supply back-up fuel control gas.	H
Supply Continuity	Part malfunctions	Potential loss of gas supply due to faults in critical parts	Determination and evaluation of critical parts	Ü
			Specific protection of care items	H+M
			Specification of critical parts to be purchased from suppliers, material acceptance according to material	Ü
			Checking the alarm panels to control critical part errors	H
			Keeping a sufficient number of spare parts for critical parts	H
			Operation management document revealing the causes of the failure in the gas supply system	H
	Errors in the maintenance system	Potential component-induced supply system failure in downstream supply systems	Operation indicating the causes of critical part welding errors management document	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Supply Continuity	Insufficient supply to areas with high addiction patients	High risk for the undernourished patient.	Identifying high risk segments	H
			Examination of the emergency supply system for high risk areas	H
			Design system to ensure a higher level of redundancy of critical components	Ü
			Controlled alarm systems to ensure that critical component failure is detected	H
			Operational Management Document addresses critical component failure issues	H
			Ability to supply localized areas	H
System Performance	Incorrect design / specification of components and pipeline systems	Inadequate supply to patient or equipment	Provide usage information	H
			Correct design of components / pipelines according to usage information	M
			Design verification according to Article 12	M
			Commissioning checks after installation	H+M
			Operational Management Document deals with periodic usage controls	H
	Inadequate corrosion protection of pipelines / components	Malfunction of pipelines / components. Leak. The collapse of the supports.	Correct design / location / protection of pipelines / components	M
			Operational Management Document deals with the periodic inspection and maintenance of the medical gas pipeline system	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
System Performance	Pressure control failure - high pressure	High pressure in the terminal unit	Correct design and location of pressure relief valves to protect against component failure	M
			Accurate design of alarm system to indicate high pressure condition	M
			Operational Management Document addresses periodic testing and maintenance of pressure relief valves	H
			Operational Management Document deals with periodic checks of high pressure alarm	H
			Operational Management Document deals with periodic inspection and maintenance of pressure regulators	H
			The Operational Management Document checks the equipment's ability to deal with pressure control system failure of the MGPS.	H
	Pressure control failure - low pressure	Low pressure in the terminal unit causes equipment failure.	Correct design of alarm system to indicate low pressure condition	M
			Operational Management Document deals with periodic checks of low pressure alarm	H
			Operational Management Document deals with periodic inspection and maintenance of pressure regulators	H

Security Target	Root cause	Dangerous Situations	Risk Control Assesstments	Responsible Institution
System Performance	Incorrect design / specification of supply sources	Insufficient supply Inadequate supply to the pipeline	Provide usage information	H
			Correct design and sizing of supply sources based on usage information and supplier's capabilities / contractual arrangements	M
			Design verification according to Article 12	M
			The following information on the commissioning controls	H+M
			The Operational Management Document deals with the periodic controls of the supply installation, location and access resources.	H
			The Operational Management Document discusses periodic usage controls to review supply resource capacity.	H
	Leak from pipes	Potential risk of fire Potential risk of suffocation Potential risk of high gas concentration Potential inadequate / reduced supply of terminal units	Commissioning the system	H+M
			Operational Management Document deals with periodic leakage checks from MGBS.	H
			Operational Management Document deals with the periodic maintenance of MGBS.	H

Security Target	Root cause	Dangerous Situations	Risk Control Assesstments	Responsible Institution
Quality of the gas delivered to the patient	Wrong specification provided to supply source	Gas delivered or produced on site that does not meet specification	Certified product supplied by the gas supplier	H
			Correct contract arrangement with the gas supplier	H
			Check that flexible connections on the manifold are correctly connected (gas-specific connection if possible)	H+M
			Check that correct labels are attached to terminal outlets and field shutoff valves.	H+M
		Gas supplied to a patient who does not have the correct specification	Check that correct marks are placed in manifold chambers, cryogenic tanks and medical gas cylinder tanks	H+M
		Wrong cylinders / mobile cryogenic tanks provided / connected in the manifold	Check that the pipelines are marked for the correct gas.	H+M
			Operational management document to determine pharmacist / Quality Control responsibilities	H
		supplied gas	Correct design of on-site gas mixing / production processes	M
			Commissioning of gas mixing / production processes in the field	H+M
			Operational Management Document to determine the correct maintenance of gas mixing / production processes operated in the field	H
			Operational Management Certificate to determine the correct test of the mixed / produced gas in the field	H

Security Target	Root cause	Dangerous Situations	Risk Control Assesstments	Responsible Institution
Quality of the gas delivered to the patient	Wrong specification provided to supply source	Gas delivered or produced on site that does not meet specification Gas provided to the patient who does not have the correct specification Wrong cylinders / mobile cryogenic tanks provided / connected in the manifold Gas supplied at wrong pressure	Tedarik kaynağını manifolda bağlamak için doğru prosedürleri belirten Operasyonel Yönetim Dokümanı	H+M
			Sahada tedarik edilen gazlar için kalite gereksinimlerini gözden geçirmek için Operasyonel Yönetim Belgesi	H
			Adaptörlerin kullanılmaması gerektiğini belirten Operasyonel Yönetim Belgesi	H
			From a big cylinder Operational Management Document stating that the transition to smaller ones should not be made and cryogenic liquid transfer should be done according to the instructions of the equipment manufacturer	H
	Pollution of gases	Gases contaminated with components not cleaned to an appropriate standard Cleaning agent remaining in component or pipelines Post-construction cleaning that does not meet specification Contamination from compressors / vacuum pumps / oxygen concentrators Oxygen boosters	Correct procedures to achieve the correct level of cleanliness to ensure proper cleaning and draining	M
			Correct test procedures established to show that conditioning systems are working correctly	H+M
			Commissioning of MGBS to ensure correct cleaning / cleaning standard	H+M
			Operational Management Document to determine correct cleaning procedures and test requirements	H
			Operational Management Document to determine the correct maintenance of gas compressors / vacuum pumps / oxygen boosters	H
			Operational Management Document to determine correct test procedures for potential contaminants in medical air	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Problem Institution
Quality of the gas delivered to the patient	Pollution of gases	Gases contaminated with components not cleaned to an appropriate standard Cleaning agent remaining in component or pipelines Post-construction cleaning that does not comply with specification Contamination from compressors / vacuum pumps / oxygen concentrators Oxygen boosters	Correct procedure to verify cleanliness of components used in MGPS	H+M
			Use components that meet the cleaning requirements in this part of ISO 7396 Correct place of entry to air compressors	H+M
			Correct operation of the splint treatment unit / sieve bed	H
	Pollution of gases	Clogging of the filters used in the system components causes a decrease in the flow rate Failure of the components (pressure regulators etc.) Gas leakage from the components or connections Air cleaning unit / screen bed malfunction	Technical specifications for correct procedures and cleaning of pipes and components and control of filters after commissioning	M
			Correct test procedures are defined to show that the filters are not blocked (and there are no excess particles in the system).	M
			Operational Management Document to determine correct filter cleaning / replacement procedures and test requirements for MGBS filters	H
			Operational Management Document to determine correct filter cleaning / replacement procedures and test requirements for medical device filters connected to MGBS	H
			Operational Management Certificate to determine the correct maintenance of the filters	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Sorumlu Kurum
Quality of the gas delivered to the patient	Ignition / decomposition of components used in MGBS	Toxic gases released into the gas stream	Check that all components used comply with ISO 15001	M
			Operational Management Certificate to ensure that all spare parts used in MGBS comply with ISO 15001	H
	Recirculation of gases in a MGBS	Loss of potential supply to the patient Possible contamination of the supply source of the gas supplied to the patient	Correct design of MGBS to prevent gas backfeeding	M
			Commissioning checks to show the performance of backflow protection devices or differential pressure settings	H+M
			Operational Management Document to determine the correct testing and maintenance of backflow protection devices and differential pressure settings	H
	Supply of wrong medical gas	Potential risk of suffocation	Operational Management Document that obeys the use of adapters	H
			Make sure there is no backflow in medical devices connected to MGBS.	H
	Cross links between MGBS	Contamination of the supply source or gas supplied to the patient	Correct design of MGBS to prevent cross connections	M
			Activation of MGBS to show that there is no cross connection	H+M
			Operational management document addresses control of cross-contamination when the system is changed / expanded.	H
System Operation	Misuse or maintenance of MGBS	Incorrect quality gas / vacuum delivered to the patient Failure to feed the patient	Define the correct procedures for each part / component of the MGBS in the Operational Management Document	H+M
			Define responsibilities for all relevant staff users of MGBS	H
			Define training requirements for all relevant staff / users of MGBS	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
System Operation	Misuse or maintenance of MGBS	Incorrect quality gas / vacuum delivered to the patient Failure to feed the patient	Make sure all area shut-off valves, control panels and alarm panels are in a suitable location and properly labeled.	H+M
			Training of all relevant staff / users of MBPS	H
			Operational Management Document stating the need to evaluate the competencies of all relevant personnel / users of MGBS and to determine the re-training requirements; training record	H
	Insufficient resources to operate and manage MGBS	Incorrect quality of gas / vacuum delivered to patient Failure to supply patient or equipment	Review staffing requirements (during and outside normal business hours) to operate MGBS safely	H
			Operational Management Document stating the need to review management requirements regularly	H
	Improper action with MGBS in an emergency	Incorrect quality gas / vacuum delivered to the patient Failure to feed the patient	Define the correct procedures for MGBS to work in an emergency	H+M
			Define emergency training requirements for all relevant staff / users of MGBS	H
			Provide emergency training for all relevant staff / users of MGBS	H
			Operational Management Document to specify the need to assess the competence of all relevant personnel / users and re-training requirements for the emergency operation of the MGBS; training record	H

Security Target	Root Cause	Dangerous Situations	Risk Control Assessments	Responsible institution
System work	Leak from pipes	Potential risk of fire. Potential risk of suffocation. Potential risk of high gas concentrations. Potential insufficient / reduced supply to the terminal units.	The need for an alarmed ambient oxygen analyzer if located inside the building.	H+M
			Operational Management Document deals with periodic leakage controls arising from MGBS.	H
Supply continuity	Loss of electrical supply to the on-site gas generation system / booster compressor.	On-site gas generation system stops operating causing loss of supply to the pipeline	Emergency Power Generator large enough to run the on-site gas generation system needed to maintain supply	H
			Sufficient back-up oxygen storage / supply source is required to allow standby generator to start to prevent supply failure	M
			Check the capacity of the emergency electricity supply	H
			Routine testing of emergency power supply	H
	Fault in on-site gas generation system / components	On-site gas generation system stops operating causing loss of supply to the pipeline	Requirement of second / third supply source (such as air compressor, valves, control panel, analyzers) to maintain supply to the pipeline system until the on-site gas generation system / component is repaired / replaced.	H
			If the second source of supply is a concentrator, there must be sufficient storage / third supply source to allow the second concentrator unit to start up and enter flow.	H
	Power loss in alarm system	Failure to alert healthcare provider of potential supply failure	UPS system to maintain power supply to the alarm system.	H+M
			Routine testing of the alarm system	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Supply continuity	Power loss to the alarm system	Failure to alert healthcare provider of potential supply failure	Operational Management Document addresses alarm failure issues	H
			Procedures to ensure that all components are returned to operating condition after power supply recovery	H
	Power loss in control panel including Analysis Panel	Failure of the on-site gas generation system	UPS system to maintain power supply to the control panel	M
			Procedures to ensure that all components are returned to operating condition after power supply reinstallation	H
	Internal piping failure at the outlet of the on-site gas generation system	Loss of supply to the pipeline resulting in high oxygen enrichment levels leading to potential fire	The need for an alarmed ambient oxygen analyzer if located inside the building.	H
	Waste gas ventilated in the Oxygen Concentrator Unit building	High nitrogen enrichment causing suffocation inside the building	The need for an alarmed ambient oxygen analyzer, if located inside the building.	H+M
	Bad location of on-site gas generation system	Potential for increased concentration of atmospheric contaminants that could lead to deterioration of screen material. Loss of product quality leading to high levels of potential toxic contaminant (such as CO) in the oxygen supply.	Oxygen monitoring requirements for pollutants to meet pharmacopoeia requirements / specification detailed in the standard	M
			Make sure the control room has adequate temperature control and ventilation.	M
			Review the room temperature control to make sure the analyzer is working properly.	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Supply Continuity	Poor location or maintenance of on-site gas generation system	Mechanical damage to supply sources leads to loss of supply. Sources of supply affected by the incident involving an adjacent facility. Possible damage to other sources of supply. The ultimate failure of the supply source. Access to all sources of supply was denied, resulting in a loss of supply.	Make sure plant rooms and manifold rooms have adequate temperature control and ventilation.	H+M
			Review the room temperature control to make sure the analyzer is working properly..	H
			Where part of the plant is located outside, the facility must be protected from mechanical damage.	H
			Field procedures to maintain access to supply sources	H
			Routine review of the location of the supply system to ensure that the system remains safe.	H
	Component failure	Potential for loss of supply due to failure of critical components.	Properties of critical components to be purchased from approved suppliers.	H+M
			Alarm systems are checked to ensure that the failure of critical components is detected.	H
			Sufficient spare parts / redundancy for critical components.	H
	Maintenance system malfunction	Possible failure of components and subsequent feeding system failure	The Operational Management Document deals with issues related to critical components.	H
	When the primary and secondary source are not available, the booster compressor cannot be used.	There is no gas for the booster compressor to compress into the oxygen reservoir 93 (third source)	Sizing the third source to container-count situations where there is no gas to be compressed (when the primary source is not available and the secondary source is closed for maintenance)	M+H
			Sizing the Oxygen Concentrator Unit to provide enough output to allow pipeline requirements to be met while providing enough gas to run the booster compressor	M
			Sizing of cylinder backup supply source to account for product availability during refilling.	M+H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Supply Continuity	Changes in oxygen demand to the right over time	Lack of oxygen available from any source of supply	Sizing the Oxygen Concentrator Unit to take into account the planned growth in oxygen use	M+H
System Performance	Incorrect design / features of components - pipeline systems	Insufficient supply to the pipeline system	Provide usage information	H
			Correct design of components / pipelines according to usage information	M
			Sizing and performance verification according to Article 12	M+H
			Operational Management Document deals with periodic usage controls.	H
	Failure of pressure control causing low pipeline pressure	Low pressure to the pipeline system / frequent switch to second source, leading to low pressure in the pipeline.	Tesisin boru hattı minimum basıncını korumak için yeterli kapasitede olmasını sağlamak için Oksijen Yoğunlaştırıcı Birimi tasarımı	M+H
			The design of the alarm system to show the low pressure condition	M
			Operational Management Document that deals with periodic controls related to low pressure alarm	H
			The Operational Management Document deals with the periodic inspection and maintenance of the Oxygen Concentrator Units.	H
	Leak from pipes	Potential risk of fire. Potential risk of suffocation. Potential risk of high gas concentrations. Potential under / reduced supply to terminal units	The need for an alarmed ambient oxygen analyzer if located inside the building	H
			Operational Management Document handles periodic leakage controls arising from MGBS.	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Quality of the gas delivered to the patient	Incorrect specification from on-site gas generation system	Gas produced in the field that does not comply with the correct technical specifications Gas supplied with wrong pressure	The responsibility of the health facility should be established and monitored by the Pharmacist (or Executive Director)	H
			The responsibility of the health facility should be established and monitored by the Pharmacist (or Executive Director)	H
			Correct design specification of production processes completed and approved	H
			Commissioning / verification of production processes completed in the field	H
			Adequate training for all employees for the correct operation of the Oxygen Concentrator Unit.	H
			Operational Management Certificate to determine the correct maintenance of the Oxygen Concentrator Unit production processes operated in the field	H
			Operational Management Certificate to determine the correct test of the gas produced in the field	H
	Pollution of gases	Gases contaminated with components not cleaned to an appropriate standard. Cleaning agent is left in the component. Non-specification-side post-construction cleaning. Contamination from oxygen concentrators. Contamination from booster compressor. Contamination from the air source. Poor operation of air purification in the system.	Correct procedures to achieve the correct level of cleanliness to ensure proper cleaning and draining.	M
			Correct test procedures established to show that conditioning systems are working correctly	M
			Commissioning of Oxygen Concentrator Units to ensure correct cleaning / cleaning stand-by	M
			Operational Management Document to determine correct cleaning procedures and test requirements	M+H
			Operational Management Document to determine the correct maintenance of gas compressors / vacuum pumps	M+H
			Operational Management Document to determine correct test procedures and test frequency, including limits for potential contaminants in the oxygen supply.	M+H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Quality of the gas delivered to the patient	Excess particles from oxygen concentrator units	Clogging of system components or used filters, leading to flow reduction. Failure of components (regulators, etc.). Gas leaking from components or connections. Improper sieve bed operation. Particles from sieve beds.	Correct maintenance / monitoring of the filter behind the sieve beds	H
			To check the correct procedure and specifications of the cleaning tube and its components and the filters after commissioning	M+H
			Correct test procedures established to show that the filters are not blocked (and no excess particles in the system).	M+H
			Operational Management Document to determine correct filter cleaning / replacement procedures and test requirements for MGBS filters.	H
			Operational Management Document defining correct filter cleaning / replacement procedures and test requirements for medical device filters connected to MGBS.	H
			Operational Management Certificate to determine the correct maintenance of the filters	H
	Ignition / decomposition of components used in on-site gas generation system	Toxic gases released into the gas stream Risk of ignition of non-metallic components when the cylinder filled from the on-site gas generation system is operated from the supply source	Check that all components used comply with ISO 15001	M
			Operational Management Certificate to ensure that all spare parts used in the on-site gas production system comply with ISO 15001	H
			Correct design features of auxiliary compressor components to ensure that partial ignition does not result in the introduction of toxic gases to patients.	M
			Correct installation of the auxiliary compressor to ensure that the temperature of the auxiliary compressor is both controlled and monitored to keep the components low enough to prevent ignition.	M

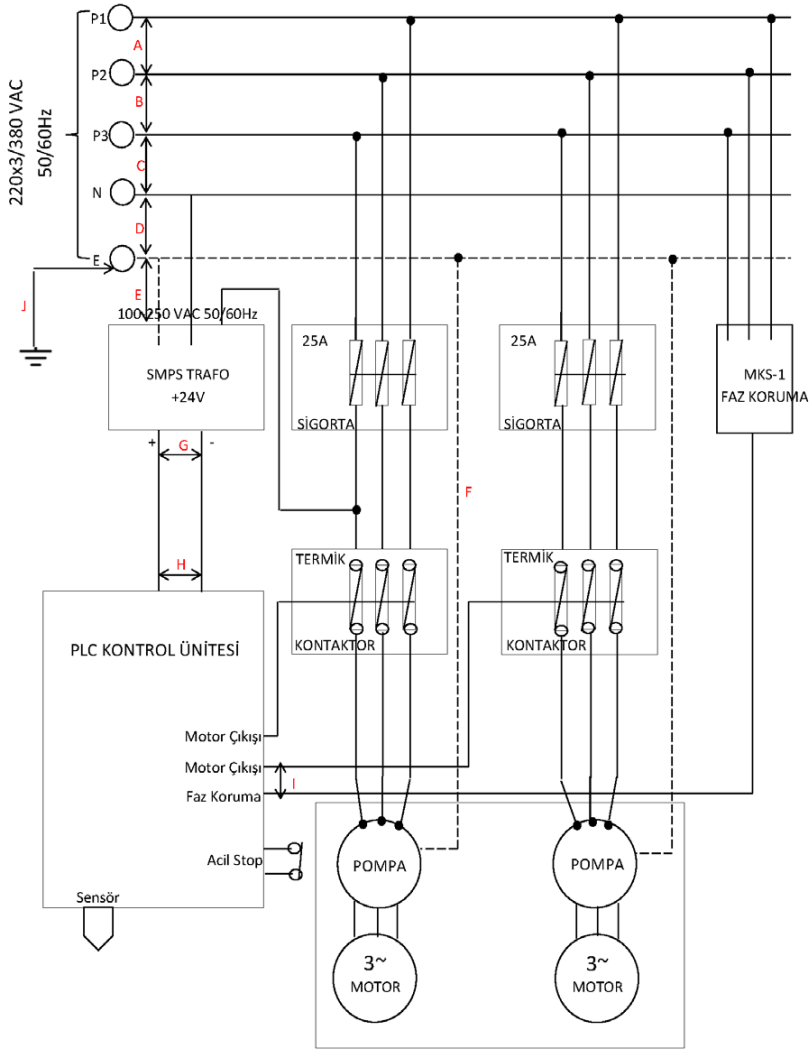
Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Quality of the gas delivered to the patient	Contamination of the gas filled into the high pressure oxygen reservoir from the booster compressor	Potential toxic gases transferred	Continuous testing of the supplied gas to back up the high pressure oxygen reservoir to ensure that the product is of the correct quality according to the pharmacopoeia specification.	H
			Operational Management Document defining the appropriate pollutants to be monitored to ensure the correct operation of the system	H
	Variability of oxygen product quality fed to the pipeline system	Lack of trend in plant performance in terms of product quality and safety	Opera-syonel Management Document that sets the requirements for documenting key / critical parameters to show the correct performance of the facility	H
			Periodic management review of facility data to ensure plant compliance and ensure no deviation in product quality	H
			Use of trend analysis to monitor screen performance to ensure that screen material is changed before product goes out of specification.	H
			Oper-Asian Management Document to define the control of the facility's nonconformities.	H
	High pressure oxygen tank filled with the booster compressor used within the boundaries of the health facility	Lack of traceability of the product System requirement for safe and efficient product recall.	Batch Management system installed to record important data and label cylinders with appropriate batch information	H
			Quality Management System in compliance with the requirements of Good Manufacturing Practices Guidelines / Pharmaceutical legislation to meet filling and traceability requirements for products.	H
			Documented procedures involving filling high pressure reservoirs	H
			Training of operators on filling high pressure reservoirs	H
			Qualification assessment of operators to ensure compliance with procedures	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Quality of the gas delivered to the patient	Improper action taken in an emergency with the on-site gas generation system	Wrong quality gas given to MGBS. Supply error to MGBS.	Define the correct procedures for on-site gas generation system operation in an emergency	M+H
			Define the emergency training requirements for all relevant personnel / users of the on-site gas generation system.	H
			Provide emergency training for all relevant personnel / users of the on-site gas generation system	H
			Operational Management document to specify the need to assess the competence of all relevant personnel / users for emergency operation of the gas production system on site and to specify the retraining requirements; enrollment training.	H
System work	Improper operation or maintenance of the on-site gas generation system	Feeding error to MGBS. Wrong quality gas given to MGBS.	Operational Management Document to define the correct preventive maintenance system to ensure the reliability of the facility	H
			Define responsibilities for all relevant personnel / users of the on-site gas generation system	H
			Define training requirements for all relevant personnel / users of the on-site gas generation system	H
			Make sure all area shut-off valves, control panels, and alarm panels are placed in a proper location and properly labeled.	H
			Train all staff / users involved in the on-site gas generation system.	H
			On-site gas generation system-Operational Management document that specifies the need to evaluate the competencies of all relevant personnel / users of the company and determines the retraining records of the training.	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
System Operation	Insufficient resources to operate and manage the on-site gas generation system	Wrong quality gas given to MGBS. Supply error to MGBS	Review personnel requirements (during and outside normal business hours) to safely operate the on-site gas generation system	H
			Operational Management document stating the need to review management requirements regularly.	H
			The availability of external maintenance services to protect the facility for both preventive and corrective maintenance.	H
Control of oxygen concentration	Using two different quality supply sources (93% against 99.5%).	Equipment cali-breezed using gas supplied in MGBS as standard gas.	Operational Management System, which defines the use of a certified cylinder as a standard to calibrate the analysis in the medical device that applies the gas to the patient.	H
			Medical devices that are not compatible for use with 93% oxygen must be labeled to indicate the special care required to ensure safe use of the device.	H
			In high-risk areas within the health facility, the oxygen concentration must be permanently monitored with alarms at certain limits.	H
			Labeling of exit points to indicate the potential quality of the delivered gas	H
			Operational Management Document to indicate the need to evaluate the competencies of all relevant personnel / users of MGBS provided by the on-site gas generation system and to determine the re-training requirements; training record	H

Security Target	Root cause	Dangerous Situations	Risk Control Assessments	Responsible Institution
Control of oxygen concentration	Use of two different quality supply sources (93% vs 99.5%)	Flow sensors used in medical devices may not be suitable for use in locations with relatively high concentrations of argon in the gas.	Medical devices 93 that are not compatible for use with oxygen should be labeled to indicate special care required to ensure safe use of the device.	H
	93% oxygen usage	High levels of argon in the gas provided for patient use at higher pressures	Prevention of oxygen 93 use in hyperbaric chambers	H
			For low fresh gas flow anesthesia, the possible accumulation of the allowable argon concentration for oxygen 93 will be taken into account. Appropriate processes will be described to keep the argon concentration at an acceptable level.	H
	Using two different quality supply sources (Oxygen 93 versus Oxygen)	Depending on the patient's condition, the oxygen concentration can have a negative effect on the patient's treatment.	Terminal units and equipment must be labeled.	H
			The health facility should ensure that the medical equipment used is compatible with 93 oxygen.	H
			Low flow oxygen systems (using 93% oxygen may cause hypoxemia due to argon accumulation in the circle system).	H
	Poor management of the on-site gas generation system	Large variation in oxygen concentration of gas produced by on-site gas generation system	Operating Document provided by the on-site gas generation system manufacturer to clearly define the operation and maintenance instructions for the correct operation of the facility. The User's Manual should indicate the level of training required to ensure patient safety.	H
			Operational Management Document covering requirements for the operation of an on-site gas generation system in Healthcare facilities, including requirements for documenting operating conditions, training and retraining requirements, and approved maintenance frequencies for major components of the facility.	H

9. ELECTRICAL CIRCUIT SCHEME



10. ELECTROMAGNETIC COMPATIBILITY (EMC) DECLARATION

Vacuum Plants require special precautions regarding EMC and should be installed and put into service according to the EMC information given below. Portable and mobile RF communications equipment (eg cell phones) can affect Vacuum Plants. The use of accessories and cables other than those specified (non-original Vacuum Plant parts) may cause increased emissions and decreased immunity of the product.

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration - Electromagnetic emissions</td></tr>
<tr><td colspan="3">Vacuum Plants are manufactured for use in the electromagnetic environment specified below. The customer or the user of the Vacuum Plant should ensure that it is used in such an environment.</td></tr>
<tr><td>Emission tests</td><td>Harmony</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>Vacuum Plants use RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference to nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">Vacuum Plants can be used in all facilities, including houses and those connected to the public low-voltage power supply that supplies buildings used for domestic purposes. suitable.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Warn</td></tr>
</table>

Recommended distances between portable and mobile RF communications equipment and Vacuum Plants

Vacuum plants are built for use in an electromagnetic environment in which radiated RF disturbances are controlled. Between the customer or the user of the vacuum plant, portable and mobile RF communication equipment (transmitters) and the vacuum plant,
They can prevent electromagnetic interference by providing the minimum distance recommended below according to the maximum output power of the communication equipment.

Vericinin anma maksimum çıkış gücü W	Distance according to the frequency of the transmitter m		
	150 kHz - 80MHz d = 1.2 P	80 MHz - 800 MHz d = 1.2 P	800 MHz - 2.5 GHz d = 2.3 P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters at maximum output power not listed above, the recommended distance d can be estimated using the equation applicable to the frequency of the transmitter in meters (m), where p is the maximum output power rating in watts (W) of the transmitter according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance applies for the higher frequency range.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation can be affected by absorption and reflection from buildings, objects and people.

Guidance and manufacturer's declaration - Electromagnetic emissions			
Vacuum plants are manufactured for use in the electromagnetic environment specified below. The customer or the user of the vacuum plant should ensure it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Performed RF IEC 61000-4-6 Radiating RF IEC 61000-4-3	3 V rms 150 kHz - 80 MHz 3 V/m 80 MHz - 2.5 GHz	3 V rms 3 V/m	No part of the vacuum plant, including cables for portable and mobile RF communications equipment, should be used closer than the recommended separation distance calculated from the equation for the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz - 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz - 2.5 GHz Where p is the maximum output power rating in watts (W) of the transmitter according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths of fixed RF transmitters detected from an electromagnetic field survey should be less than the compliance level in each frequency range. Interference may occur near equipment marked with the following symbol: 
NOTE 1 At 80 MHz and for the higher frequency range at 800 MHz, the separation distance applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation can be affected by absorption and reflection from buildings, objects and people.			
a Field strengths from fixed transmitters such as base stations for radio (cellular / cordless telephone) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast can be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the vacuum plant is used exceeds the applicable RF Compliance level above, observation should be made to confirm normal operation of the vacuum plant. If abnormal performance is observed, additional measures may be required, such as rerouting or relocating the vacuum plant. b Frequency range should be above 150 kHz - 80 MHz, field strengths should be less than 3 V / m.			

Guidance and manufacturer's declaration - Electromagnetic emissions			
The vacuum plant is manufactured for use in the electromagnetic environment specified below. The customer or the user of the vacuum plant should ensure it is used in such an environment.			
Immune testing	IEC 60601 test level	Compliance level	Electromagnetic environment - guide
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic. Relative humidity when the floor is covered with synthetic material must be at least 30%.
Electric fast transient / burst IEC 61000-4-4	± 2 kV for electricity supply lines ± 1 kV For input / output lines	Not available	Mains power quality should be equivalent to that of a normal commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Line to line ±2 kV Line to ground	Not available	Mains power quality should be equivalent to that of a normal commercial or hospital environment
Voltage dips (dips), short interference and voltage variations on electricity supply input lines IEC 61000-4-11	<5% UT (At UT> 95% dip UT) for 0.5 return 40% UT (60% dip in UT) for 5 rotations 70% UT (30% dip in UT) for 25 turns <5% UT (> 95% in UT dip) for 5 s	Not available	Mains power quality should be equivalent to that of a normal commercial or hospital environment. It is recommended that the A&D Product be operated from an uninterruptible power supply or battery in case the user of the A&D product requires continuous activity during power outages.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at the specification levels of a typical location in a normal commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

11. GERİ DÖNÜŞÜM

When your vacuum plant has reached the end of its life or you want to replace any part of the product, check the recyclability of each part.

Since your Vacuum Plant is used for the treatment and alleviation of diseases, it falls into the category of electrical and electronic goods according to the Regulation on Control of Waste Electrical and Electronic Equipment and the relevant directives of the European Parliament and Council Directive (WEEE) dated July 4, 2012 and numbered 2012/19 / EU. Therefore, when your device has reached the end of its useful life, take it to or have it taken to collection points created by distributors, municipalities, manufacturers or processing facilities. In case of need, refer to the Regulation on Control of Waste Electrical and Electronic Equipment.

Tanks used in vacuum plants should be considered as "Contaminated Medical Waste".

Recycle used oils, greases and filters through an organization approved by the country in which the equipment is used.

Take every possible measure to protect the environment. In particular, all waste fluids must be recovered and recycled. Never throw these liquids directly into the environment.

For more information about recycling, please contact relevant institutions and organizations or visit their websites that provide information about recycling.

Headquarters & Factory
ÜZÜMCÜ TIBBİ CİHAZ VE MEDİKAL GAZ SİSTEMLERİ SANAYİ VE TİCARET A.Ş.
OĞULBEY MAHALLESİ 3058. CADDE NO:2
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İstanbul Region Headquarters
Oruç Reis Mah. Tekstilkent Cad. Tekstilkent Ticaret Merkezi
10-AN NO: Z09 (A7 BLOK NO: 19) Esenler-İSTANBUL, TURKEY

ÜZÜMCÜ
MEDICAL EQUIPMENT

ÜZÜMCÜ

Headquarters & Factory
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KL-14 TR EN UZUMCU 26.10.2020 / REV.01

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

SERTİFİKA
CERTIFICATE

TS EN ISO 13485:2016 Tıbbi Cihazlar Kalite Yönetim Sistemi
Medical Devices Quality Management System as per TS EN ISO 13485:2016

In accordance with BBS procedures, it is hereby certified that

ÜZÜMCÜ

ÜZÜMCÜ TIBBİ CİHAZ VE MEDİKAL GAZ SİSTEMLERİ SAN. VE TİC. A.Ş.

Oğulbey Mahallesi 3058 Cadde No:2 Gölbaşı / ANKARA / 06830

BBS prosedürlerine göre yukarıda belirtilen standart şartlarını karşıladığını kanıtlamıştır.
Applies a management system in line with the above standard for the following scope

Kapsam

Ameliyathane ekipmanları, yoğun bakım ve acil servis ekipmanları, hasta odası ve klinik ekipmanları, sterilizasyon ve paslanmaz çelik ekipmanları, medikal gaz sistemi ve ekipmanları, hastane, ambulans ve laboratuvarların ekipmanlarının tasarımı, geliştirilmesi, üretimi, montajı, dağıtımı ve servisi.

Scope

Operating room equipment, intensive care and emergency service equipment, patient room and clinical equipment, sterilization and stainless-steel equipment, medical gas system and equipment, hospital, design of ambulance and laboratories equipment, development, manufacture, assembly, distribution and service of equipment.

Sertifika No / *Ceritificate No* 1256-01

İlk Belge Tarihi / *Initial Certification* 28.04.2022
Belge Geçerlilik Tarihi / *Valid Until* 27.04.2025

Belgelendirme Kuruluşu / *Certification Body*
BBS A.Ş.

Ankara, 28.04.2022

Belgelendirme BBS tetkik ve belgelendirme prosedürlerine uygun olarak gerçekleşmiştir ve düzenli gözetim tetkiklerine tabidir.
Certification was conducted in accordance with BBS auditing and certification procedures and is subject to regular surveillance audits.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

TÜRKAK
Medikal Cihazlar
TS EN ISO 13485: 2016
AB-0021-YS

TÜRKAK BDS NO
YS-2505-590C

Bu sertifikanın geçerlilik durumu www.bbsas.com.tr ve tbds.turkak.org.tr adreslerinden doğrulanabilir.
Belge üzerindeki karekod QR okuyucu ile okutulmak suretiyle de doğrulama yapılabilir.
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 / TÜRKİYE
www.bbsas.com.tr

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Üzümcü Tıbbi Cihaz Ve Medikal Gaz Sistemleri San. ve Tic. A.Ş.
Company Address	: Oğulbey Mah. Kumludere Cad. No:1/1A Gölbaşı ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Medical Gas System and Electrosurgical Products - Class IIb, IIa
GMDN	: 10217, 42549, 36271, 35630, 36810, 37512, 34849, 47860, 47860, 43438, 44809, 15615, 36778, 35030, 11067

Product Types are attached.

Certificate Number	: M.2019.106.12408
Report Number	: MD.3754.IB
Initial Assessment Date	: 28.05.2019
Registration Date	: 09.08.2019
Revision Date /No	: 26.08.2020/02
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

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This document containing 3 (three) pages is the Annex of the Certificate with the revision number 02, with the number M.2019.106.12408 and with the registration date of 09.08.2019 and with the revision date of 26.08.2020 issued for "Üzümcü Tıbbi Cihaz Ve Medikal Gaz Sistemleri San. ve Tic. A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Medical Gas Systems					
Flowmeter - Class IIb GMDN: 42549					
Models					
1200.05	1200.10	1200.15	1200.25	1200.30	1200.00B
1200.00N	1200.00E	1200.05U	1200.10U	1200.15U	1274.00
1200.20U	1220.05	1220.10	1220.15	1220.20	1222.05
1230.05	1230.10	1230.15	1270.00	1273.00	
Bed Head Units and Pendants **Bed Head Units – Class IIb GMDN: 36271**					
1000.10	1000.60	1030.10	1035.20	1035.75	1040.30
1000.20	1000.70	1030.20	1035.30	1040.09	1045.10
1000.30	1000.85	1030.30	1035.55	1040.10	1045.20
1000.50	1000.95	1035.10	1035.65	1040.20	1065.10
1065.11	1065.13	1065.15	1065.30	1070.30	
1065.12	1065.14	1065.20	1068.10	1070.50	
Bed Head Units and Pendants **Pendants - Sınıf IIb GMDN: 35630,36810**					
5070.30	5070.50	5070.65	5070.75L	5070.81	1085.80
5070.40	5070.60	5070.75	5070.80	5075.45	1085.90
5070.45	5070.61	5070.76	5070.80L	5075.50	
Medical Gas Terminal Units / Medical Gas Outlets and Probes / Medical Gas Outlets - Class IIb GMDN: 36271					
Models					
1001.05	1001.59	1003.59	1004.58	1005.52	1001.05
1001.50	1003.50	1004.05	1004.59	1005.58	1001.50
1001.51	1003.51	1004.50	1005.05	1005.59	1001.51
1001.52	1003.52	1004.51	1005.50	1008.51	1001.52
1001.58	1003.58	1004.52	1005.51		1001.58
Medical Gas Terminal Units / Medical Gas Outlets and Probes / Vacuum Outlets - Class IIb GMDN: 37512					
Models					
1002.05	1002.51	1002.58	1002.50	1002.52	1002.59
Medical Gas Terminal Units / Medical Gas Outlets and Probes / AGSS - Anaesthetic Gas Scavenging Outlets and Probes **- Class IIb GMDN: 34849**					
Models					
1007.05	1007.10	1017.10	1607.05	1607.10	2027.10

Medical Gas Terminal Units / Medical Gas Outlets and Probes / Probes for Compressed Medical Gases **- Class IIb GMDN: 36271**					
Models					
1601.05	1603.10	1604.15	1241.05	1243.10	1245.15
1601.10	1603.15	1605.05	1241.10	1243.15	1246.05
1601.15	1604.05	1605.10	1241.15	1245.05	1246.10
1603.05	1604.10	1605.15	1243.05	1245.10	1246.15
Medical Gas Terminal Units / Medical Gas Outlets and Probes / Probes for Vacuum **- Class IIb GMDN: 37512**					
Models					
1602.05	1602.15	1242.10	1244.05	1244.15	
1602.10	1242.05	1242.15	1244.10		

UDEM APPROVED 2292

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

This document containing 3 (three) pages is the Annex of the Certificate with the revision number 02, with the number M.2019.106.12408 and with the registration date of 09.08.2019 and with the revision date of 26.08.2020 issued for "Üzümcü Tıbbi Cihaz Ve Medikal Gaz Sistemleri San. ve Tic. A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Regulators for Use with Medical Gases / Pressure Regulators for Terminal Units (OTC included) - Class IIb GMDN: 47860				
Models				
1401.05	1403.05	1404.05	1405.05	OTC-50
1401.10	1403.10	1404.10	1405.10	OTC-51
1401.15	1403.15	1404.15	1405.15	OTC-52
1401.05	1403.05	1404.05	1405.05	OTC-50

Regulators for Use with Medical Gases / High Pressure Reducers - Class IIb GMDN: 47860			
Models			
4000.10	4000.15	4000.30	4000.80
4000.10A	4000.15A	4000.30A	4000.80A

Regulators for Use with Medical Gases / Regulators for Use with Cylinders - Class IIb GMDN: 43438		
Models		
OBR-50	OBR-51	OBR-80

Regulators for Use with Medical Gases / Regulators for Use with Terminal Units - Class IIb GMDN: 44809					
Models					
1402.05	1402.10R	1422.10	1520.00D		
1402.10	1402.15R	1422.15	1420.20D		
1402.15	1420.20N	1422.20	1420.20B		
1402.05R	1422.05	1520.00B	1520.00N		

Pipelines and Stations for Medical Gases / Area Gas Control Boxes- Class IIb GMDN: 36271					
Models					
956280601	956280603	956280901	956280903	956281201	956281203
956281501	956281503	956280302	956280304	956280602	956280604
956280902	956280904	956281202	956281204	956281502	956281504
956280301	956280303				

Pipelines and Stations for Medical Gases / Oxygen Station- Class IIb GMDN: 36271				
Models				
MOS-4M	MOS-10	MOS-16	MOS-30	MTO-2
MOS-6	MOS-11	MOS-20	MOS-40	

Pipelines and Stations for Medical Gases / Nitrous Oxide Station- Class IIb GMDN: 36271				
Models				
MAS-4M	MAS-10	MAS-16	MAS-30	MTA-2
MAS-6	MAS-11	MAS-20	MAS-40	

Pipelines and Stations for Vacuum / Vacuum Station (Vertical)- Class IIb GMDN: 15615		
Models		
VRD-42	VRD-102	VRD-202
VRT-43	VRT-103	VRT-203

Pipelines and Stations for Vacuum / Vacuum Station (Horizantal)- Class IIb GMDN: 15615		
Models		
VYD-42	VYD-102	VYD-202
VYT-43	VYT-103	VYT-203

Pipelines and Stations for Vacuum / Vacuum Station (Mini)- Class IIb GMDN: 15615
Models
VPY-70

Central Vacuum Trolley- Class IIa GMDN: 36778
Models

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This document containing 3 (three) pages is the Annex of the Certificate with the revision number 02, with the number M.2019.106.12408 and with the registration date of 09.08.2019 and with the revision date of 26.08.2020 issued for "Üzümcü Tıbbi Cihaz Ve Medikal Gaz Sistemleri San. ve Tic. A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

30400	30402	30403	30405
Electrosurgical Units			
Electrosurgical Cautery- Class IIb GMDN: 35030			
Models			
EK-160	EK-250	EK-410	
Cryotheraphy Device - Class IIa GMDN: 11067			
Models			
KRY-10	KRY-10S		
Surgical Suctions Mobile Series – Class IIa GMDN: 10217			
Models			
Amb	PA-1R	PA-2	PA-2S
Surgical Suctions Novela Series – Class IIa GMDN: 10217			
Models			
Novela	Novela Extractor	Vela	

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