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Report Preparation Date:	10.03.2022	**Last Update Date:**	24.06.2022	**Update No:**	01
Product Name/Model:	Medical Oxygen Production and Storage System				
Reason for Choosing the Product:	Since there is only a difference in the capacity of the tanks as a model difference in our product, critical product selection was not made.				
Latest Update Content:	1st update carried out within the scope of regulation of hedging methods on 24.06.2022				

Abbreviations:

GT: Safe design and manufacturing to be applied due to the nature of the product
KT: Protective measures in the medical device itself or in the manufacturing process
GV: Safety information and training for users where appropriate

Hazard Types Abbreviations

RAE	Acoustic Energy **(RAE)**	**RB**	Biological **(RB)**
REE	Electromagnetic Energy **(REE)**	**RK**	Chemical **(RK)**
RME	Mechanical Energy **(RME)**	**RM**	Immunological **(RI)**
RPE	Potential Energy **(RPE)**	**RV**	Data **(RV)**
RIE	Radiant Energy **(RIE)**	**RD**	Delivery/Delivery **(RD)**
RTE	Thermal Energy **(RTE)**	**RT**	Diagnosis **(RT)**
N/A	Not applicable (No Hazard)	**RI**	Functionality (**(RI)**

Name of the product:
Medical Oxygen Production and Storage System

Product Brand/Model/Size and GMDN Codes:
See: APPENDIX-1 Product Model and GMDN Code Table

Usage Areas and Purpose of Use:
It is used in bedside units in hospitals, in cases where the patient has lung failure and in anesthesia applications, in order to provide the oxygen needed by the patient, to produce medical oxygen, to store it and to give it to the medical gas power plants of the hospital.

Contraindications:
It has no known contraindications.

Complications:
It has no known complications.

Side effects:
It has no known side effects.

Product Life:
Our product does not have a certain life span and spare parts will be available for the purpose of eliminating malfunctions/problems that may occur in the device for 10 years following the last device sale. All filters, carbon tower, compressor and dryer spare parts, oxygen sensor and pneumatic valves of the device should be replaced at required intervals. It is recommended to replace the UPS in the device every two years. At the end of 10 years, the device can continue to be used by replacing the zeolites of the system and performing the above-mentioned periodic maintenance.

Working Principle of the Device:
The medical oxygen production and storage system is a system that filters the air it takes from outside with the help of zeolite stones, selects and stores the oxygen and throws the remaining gases out with the help of exhaust.

The compressor in the system absorbs the air in the environment , this air is passed through the water separator and the amount of water in it is reduced. This air is then passed through the coarse particle filter and is purified from the particles in it. Afterwards, the air sent to the dryer is thoroughly dehumidified and sent to the air tank for storage. If water has reached the air tank, the water is automatically discharged from the automatic water separator at the bottom of the tank. The dry air coming out of the air tank is filtered in the Particle Filter and the Carbon Tower, which has a Water Filter, respectively, and transferred to the generator in a dry and oil-free manner.

The air reaching the generator is directed to the right tank at the right time with the help of the pneumatic valves on the device, allowing the oxygen to be stored and the nitrogen to be released back into the atmosphere. Nitrogen gas in the air entering the generator establishes a temporary bond with the zeolite stones, although this bond is also established with oxygen, it occurs at a much lower rate than nitrogen. For this reason, over time, oxygen rises and comes to the exit of the zeolite tank, while nitrogen remains attached to the zeolite stones. The oxygen coming to the upper part of the generator is sent to the oxygen tank with the help of pneumatic valves. Then, the gases that are mostly formed by Nitrogen gas trapped in the zeolite stones are exhausted and thrown out.

Risk Code/Risk Matrix	Damage	Hazard/Hazards	Potential Cause (Danger and Event Sequence)	Effect	Possibility	pact*Probabilit	Risk Control	Hedging Method	Effect	Possibility	pact*Probabilit	Residual Risk Evaluation	Benefit Effect	Possibility	ment*Probabilit
R1/REE	User damage	Electrical Energy	Electric shock due to Electric Leakage in the device	4	2	8	☒ GT ☒ KT ☐ GV	The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device. During the design of our device, components were supplied by taking into account the electrical risks and our device was designed in such a way that it would not harm the user due to electrical leakage. **(See:** Design File) The production processes of our device are carried out in accordance with the Production and Quality Control Procedure, and the conformity of the product is ensured by both the quality controls to be made during production and the quality controls performed by us after production. Release approval is granted if all control results are positive. Otherwise, no device is allowed to output. In addition, after the device production is completed, controls are carried out in accordance with 60601-1 standards, and the sale of devices that are not suitable as a result of the control is not allowed. **(See:** Production and Quality Control Procedure) The electrical and magnetic safety of our device is verified by the test study carried out in accordance with EN 60601-1 and EN 60601-1-2 Standards in independent accredited institutions. When the results of the tests carried out in independent accredited laboratories are examined, it has been seen and verified that our device is electrically and magnetically safe.	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25

R2/REE	User damage	Electrical Energy	Electromagnetic emission due to the creation of an electromagnetic field around the device at a level that will affect the users around it.	4	2	8	☒ GT ☒ KT ☐ GV	The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device. During the design of our device, components were supplied considering the electrical risks and our device was designed in such a way that it would not harm the user due to the magnetic field. **(See:** Design File) The electrical and magnetic safety of our device is verified by the test study carried out in accordance with EN 60601-1 and EN 60601-1-2 Standards in independent accredited institutions. When the results of the tests carried out in independent accredited laboratories are examined, it has been seen and verified that our device is electrically and magnetically safe.	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25
R3/REE	Damage to the Device	Electrical Energy	Occurrence of Electric Leakage in the Device	4	2	8	☒ GT ☒ KT ☐ GV	The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, the health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device. During the design of our device, components were supplied considering the electrical risks, and thanks to these components and grounding systems, our device was designed in such a way that it would not be affected by electrical leakages. **(See:** Design File) The production processes of our device are carried out in accordance with the Production and Quality Control Procedure, and the conformity of the product is ensured by both the quality controls to be made during production and the quality controls performed by us after production. Release approval is granted if all control results are positive. Otherwise, no device is allowed to output. In addition, after the device production is completed, controls are carried out in accordance with 60601-1 standards, and the sale of devices that are not suitable as a result of the control is not allowed. **(See:** Production and Quality Control Procedure) The electrical and magnetic safety of our device is verified by the test study carried out in accordance with EN 60601-1 and EN 60601-1-2 Standards in independent accredited institutions. When the results of the tests carried out in independent accredited laboratories are examined, it has been seen and verified that our device is electrically and magnetically safe.	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25

R3/REE	Damage to the Device	Electrical Energy	High current coming to the device due to fluctuations in the mains voltage	4	2	8	☒ GT ☒ KT ☐ GV	The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device. During the design of our device, components were supplied considering the electrical risks. While designing the device, it was taken into consideration that the device should have a fuse, EMI filter and residual current relay in order not to be affected by the changes in the mains voltage, and the device was designed accordingly. **(See:** Design File) The production processes of our device are carried out in accordance with the Production and Quality Control Procedure, and the conformity of the product is ensured by both the quality controls to be made during production and the quality controls performed by us after production. Release approval is granted if all control results are positive. Otherwise, no device is allowed to output. **(See:** Production and Quality Control Procedure) The electrical and magnetic safety of our device is verified by the test study carried out in accordance with EN 60601-1 and EN 60601-1-2 Standards in independent accredited institutions. When the results of the tests carried out in independent accredited laboratories are examined, it has been seen and verified that our device is electrically and magnetically safe.	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25
R4/REE	Damage to other devices in the vicinity	Electrical Energy	Creating an electromagnetic field around the device at a level that will affect other devices around it	4	2	8	☒ GT ☒ KT ☐ GV	The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device. During the design of our device, components were supplied considering the electrical risks and it was designed in a way that it would not affect other devices around our device by creating a magnetic field. **(See:** Design File) The electrical and magnetic safety of our device is verified by the test study carried out in accordance with EN 60601-1 and EN 60601-1-2 Standards in independent accredited institutions. When the results of the tests carried out in independent accredited laboratories are examined, it has been seen and verified that our device is electrically and magnetically safe.	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25

R5/RPE	Injury or Death of the User and Other Persons Around the Device	Potential energy	Tank Explosion Due to High Pressure	5	2	10	☒ GT ☒ KT ☐ GV	The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device. **(See:** Design File) The production processes of our device are carried out in accordance with the Production and Quality Control Procedure, and the conformity of the product is ensured by both the quality controls to be made during production and the quality controls performed by us after production. Release approval is granted if all control results are positive. Otherwise, no device is allowed to output. **(See:** Production and Quality Control Procedure) The purchase of the tanks used in the production of our device is carried out by us in accordance with the PR.06 Procedure and the tanks that reach us are subjected to the quality control process in accordance with the PR.06 Procedure. When purchasing tanks, it is noted that they must be CE certified according to the 2014/68 EU Pressure Vessels directive and that the tank to be purchased must have been tested by the supplier at a pressure of at least 1.5 times the working pressure declared by us. While purchasing the tanks, CE documents and test reports are obtained from the suppliers and checked. Tanks that are found to be unsuitable as a result of the control are not accepted by us. *In addition, there are pressure valves integrated into all pressure tanks. These valves open at the upper limit of the working pressure of the high pressure tanks and discharge the high pressure air before it reaches the burst pressure.*	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25

R6/RI	Patient Injury	Functionality	Oxygen purity coming out of the device is less than 90%	4	2	8	☒ GT ☒ KT ☐ GV	The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device. In addition, it is necessary to ensure that the Oxygen purity value, which is the critical value during device design, is 93% ± 3%. *Especially, oil and moisture/water access to zeolite stones should be at minimum level, for this, there are filters in the system that filter oil and water in different pore sizes and dryers that reduce the dew point of the air to +3 degrees.* The maintenance and replacement period of these filters is reported to the user with the user manual prepared in accordance with the EN 1041 Standard, which is given to the user each time a sale is made. In addition, the purity values of the oxygen produced are measured with the oxygen sensor in the device, and when the desired value is exceeded, the system warns the user by giving an alarm both visually and audibly on the touch screen after the production is terminated. Since the production has been terminated, no oxygen-purity gas is sent to the patient, which is out of the standard. **(See:** Design File) **(See:** User Manual) The production processes of our device are carried out in accordance with the Production and Quality Control Procedure, and the conformity of the product is ensured by both the quality controls to be made during production and the quality controls performed by us after production, including the step of checking the oxygen purity. Release approval is granted if all control results are positive. The output of the devices whose oxygen purity value is outside the limit as a result of the control is not allowed. **(See:** Production and Quality Control Procedure)	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25

R7/RI	User gas poisoning	Functionality	Increase in nitrogen value in the environment due to inadequate ventilation	4	2	8	☒ GT ☒ KT ☐ GV	The User Manuals prepared by us on the basis of the EN 1041 Standard are communicated to the user at every device sale, and it is stated that the ventilation system will be carried out together with the health institution and the environment where the device is located should be well ventilated under the title of "Ventilation" in the Specifications section of the device. (**See** : User Manual) In addition, the device is installed by our technical service personnel in accordance with the PR.14 Technical Service Procedure, and the device is installed after checking the compliance of the ventilation conditions during the installation. Thanks to the air outlets, it is released from the exhaust to the atmosphere. *If the system is to be installed in narrow environments such as containers, nitrogen gas is taken into a channel and it is not allowed to leave nitrogen inside the container, it is thrown directly into the atmosphere.*	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25
R8/RI	Damage to the Device or User	Functionality	Incorrect use of the device	4	2	8	☐ GT ☐ KT ☒ GV	The User Manuals, prepared by us on the basis of EN 1041 Standard, are delivered to the user at every device sale, and all the details about the use of the device, operating principle of the device, operating procedure, alarm conditions and what the user should do in such cases and troubleshooting steps are detailed in the manual. takes. (**See** : User Manual)	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R9/RI	Failure to obtain oxygen from the device	Functionality	Failure of the compressor suction kit used in the device	4	2	8	☐ GT ☒ KT ☒ GV	All components purchased from suppliers with whom critical supplier contracts have been signed in accordance with the NBOG 2010 Guidelines in our company are checked by us in accordance with the PR.06 Procedure after each purchase. Products that are found to be unsuitable during the input controls are not accepted into the warehouse. In addition, according to the FR.07.08 Quality Control Form after production, the compatibility of the compressor is controlled by operating the compressor together with the system during the 8-hour test period performed by us for each batch of device, and unsuitable product output is not allowed.	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25

R10/RI	Failure of the device to produce oxygen at the desired purity	Functionality	The dryer in the system is not suitable	4	2	8	☐ GT ☒ KT ☒ GV	All components purchased from suppliers with whom critical supplier contracts are signed in accordance with the NBOG 2010 Guidelines in our company are checked by us in accordance with the R.06 Procedure after each purchase. Products that are found to be unsuitable during the input controls are not accepted into the warehouse. In addition, according to the FR.07.08 Quality Control Form after production, the suitability of the dryer is controlled by operating the dryer together with the system during the 8-hour test period performed by us for each batch of device, and unsuitable product output is not allowed.	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25
R11/RI	Failure of the product to function as a result of Oxygen/Air leakage in the device	Functionality	Incorrect hose and pipe connections	4	2	8	☐ GT ☒ KT ☒ GV	The production processes of our device are carried out in accordance with the Production and Quality Control Procedure, and the conformity of the product is ensured by both the quality controls to be made during production and the quality controls performed by us after production. Release approval is granted if all control results are positive. In cases where the hose and pipe connections are not made correctly as a result of the control, the output of the devices is not allowed. **(See:** Production and Quality Control Procedure) In addition, the device is installed by our technical service personnel in accordance with the P.14 Technical Service Procedure, and the device is installed after checking the suitability of the hose and pipe connections during the installation. The device cannot be operated without making sure that the hose and pipe connections are correct.	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25
R12/RAE	Hearing loss of people around the device	Acoustic Energy	Too noisy operation of the device	4	2	8	☒ GT ☐ KT ☐ GV	The only component that will cause noise in the system is the compressor, and this critical component is purchased from the critical supplier with whom a critical supplier contract has been concluded in accordance with the specified regulations. The noise threshold that will cause the person's hearing loss is 85 db, and the compressor used in the device that will cause the noise is max. It is limited to 80 db by the manufacturer and this value is specified in the manufacturer's catalog that comes with the compressor. In addition, there is no need for a fixed operator while the device is operating, and there will be people around the device only during maintenance and routine control. *Finally, in order to verify the safety and performance steps of our device, the noise and vibration conditions of the device are also tested by an independent accredited laboratory in accordance with the EN 60601-1 standard. When the results of the tests carried out in independent accredited laboratories are examined, it has been seen and verified that our device does not emit high noise.*	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25

R13/RAE	Damage to the device	Acoustic Energy	The device emits high vibration while operating	4	2	8	☒ GT ☐ KT ☐ GV	The only component that will cause noise in the system is the compressor, and this critical component is purchased from the critical supplier with whom a critical supplier contract has been concluded in accordance with the specified regulations. The noise threshold that will cause the person's hearing loss is 85 db, and the compressor used in the device that will cause the noise is max. It is limited to 80 db by the manufacturer and this value is specified in the manufacturer's catalog that comes with the compressor. In addition, there is no need for a fixed operator while the device is operating, and there will be people around the device only during maintenance and routine control. *Finally, in order to verify the safety and performance steps of our device, the noise and vibration conditions of the device are also tested by an independent accredited laboratory in accordance with the EN 60601-1 standard. When the results of the tests carried out in independent accredited laboratories are examined, it has been seen and verified that our device does not emit high noise.*	4	one	4	The risk determined by the measures taken by us has been reduced to the minimum levels that can be reduced.	5	5	25
R14/RI	Failure of device function	Functionality	The user does not know what to do even though there is a problem with the compressor during use	4	2	8	☐ GT ☐ KT ☒ GV	The User Manuals, prepared by us on the basis of EN 1041 Standard, are delivered to the user at every device sale, and all problems, including compressor failures, during the use of the device and what the user should do as troubleshooting steps in the face of these problems are detailed in the manual. (**See** : User Manual)	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R15/RI	Damage to the Device	Functionality	Failure to perform routine maintenance activities in a timely manner or not knowing the technical service call time(s) by the user	4	2	8	☐ GT ☐ KT ☒ GV	The User Manuals prepared by us on the basis of EN 1041 Standard are delivered to the user at every device sale, and detailed information is given to the users, including the maintenance situations, cleaning situations, calibration situations and the replacement periods of the components in the system that should be done by the user during the use of the device. (**See** : User Manual) In addition, a warning screen appears on the screen, which warns the user, on the last 250 hours of software maintenance in the system. Even if this screen is turned off, it reappears on the screen every 50 hours and warns the user to perform maintenance.	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25

R16/RI	Damage to the Device	Functionality	Failure to comply with the rules to be followed during transportation	4	2	8	☐ GT ☐ KT ☒ GV	Product shipment by us is carried out in accordance with the PR.08 Warehouse and Shipment Procedure. Warnings to be taken into account by the user during the transportation of the product are presented to the user in the "Product Storage and Shipping Conditions" section of the user manuals prepared in accordance with the EN 1041 Standard. (**See** User Manual)	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R17/RI	*Failure of the Device to Perform its Function*	Functionality	*Damage to the device*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, the " Sumer Oxyfresh system " specified under the "Warnings and Precautions" heading of the User Manual should be thoroughly examined for signs of damage to the unit. If there are signs of external or internal damage, this should be reported to Sümer AŞ immediately. With the " warning, users are warned against unfavorable situations.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R18/RI	*Failure of the Device to Perform its Function*	Functionality	*Not replacing expired components*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, if the parts and units included in the "Medical Oxygen Production and Storage System" specified under the "Warnings and Precautions" heading of the User's Manual are no longer safe or their usage period has expired, these parts should be replaced. " and " The filtration method has an important place to ensure oxygen purity. When the period comes, care should be taken to change the filter of the system and to ensure that the filter to be used has the same characteristics as the first filters of the system. Users are warned against unfavorable situations with " warnings.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R19/RI	*Harm of Patients*	Functionality	*The tanks and piping systems used in the device are not compatible with oxygen.*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, the tanks and piping systems used for the production and storage of medical oxygen must be compatible with oxygen. With the " warning, users are warned against unfavorable situations.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25

R20/RI	*User Harm*	Functionality	*Not removing the exhaust gas from the device from the environment*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, the "Exhaust gas from the oxygen generator, which is stated under the "Warnings and Precautions" heading of the User's Manual, should be removed from the room where the device is operating, and the room where the system is installed should always be well ventilated. Failure to do so may result in serious damage. With the ” warning, users are warned against unfavorable situations.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R21/RI	*Damage to the Device*	Functionality	*The pressure regulator is not installed in the system and the pressure cannot be adjusted.*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, it should be ensured that the "Pressure Regulator" specified under the "Warnings and Precautions" heading of the User's Manual is attached to the system. Care should be taken that the pressure is not higher than the specified de-sign pressure. With the ” warning, users are warned against unfavorable situations.* *Pressure regulators are used as standard in each of our de-vices. Especially the regulator on the side of the air inlet is adjusted at the factory during the tests and fixed by tighten-ing the bolt on it. Thus, our customers are prevented from accidentally changing this setting.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R22/RI	*Combustion of oxygen and explosion of the tank*	Functionality	*Smoking or an open flame source in the environment where the device is operating*	5	2	10	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition , it should be ensured that there are no cigarettes or open flames in the environment while the system is operat-ing , which is stated under the "Warnings and Precautions" heading of the User's Manual . Protective equipment should be used during work. With the ” warning, users are warned against unfavorable situations.* *Oxygen is a burning gas, not a flammable gas. In oxygen generators, the oxygen works in a closed circuit, that is, the produced oxygen is transmitted directly to the hospital through the pipes. In this sense, oxygen is not in direct con-tact with the open environment.*	5	2	10	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25

R23/RI	*Fire or explosion of the device*	Functionality	*Not cleaning the pipes and tanks in the system*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition , attention should be paid to the cleaning of pipes and tanks in the system so that the device does not cause fire or explosion, which is stated under the heading "Warnings and Precautions" in the User's Manual . With the ” warning, users are warned against unfavorable situations.* *The device operates in closed circuit. In other words, the produced oxygen is sent to the hospital via pipelines. Oxygen is known to burn under high pressure (10 barg and above) when interacting with petroleum-based products. However, the working pressure of our product is below 6 barg and it is not possible to spontaneously explode or burn at these pressures.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R24/RI	*User Harm*	Functionality	*Failure to perform electrical maintenance of the device*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, the “ System includes electrical connections ” specified under the “Warnings and Precautions” heading of the User Manual . In order to avoid hazards, the electrical maintenance of the device should be performed by trained or authorized personnel. With the ” warning, users are warned against unfavorable situations.* *The electrical diagram is presented to the customer and detailed information about all connections is given.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R25/RI	*Failure of the Device to Perform its Function*	Functionality	*Failure to perform electrical maintenance of the device*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, the “ System includes electrical connections ” specified under the “Warnings and Precautions” heading of the User Manual . In order to avoid hazards, the electrical maintenance of the device should be performed by trained or authorized personnel. With the ” warning, users are warned against unfavorable situations.* *The electrical diagram is presented to the customer and detailed information about all connections is given.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25

R26/RI	*User Harm*	Functionality	*Touching heated parts of the device with bare hands*	*4*	*2*	*8*	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition , there are parts that overheat in the device , which is stated under the "Warnings and Precautions" heading of the User's Guide . Touching these parts may cause burns and injuries to the user. These parts should not be touched without using protective equipment. With the ” warning, users are warned against unfavorable situations.* *There are two parts in the device that can reach high temperatures. One of them is the compressor and the other is the zirconium oxygen sensor. There are temperature warning symbols at the necessary points on the compressor. The zirconium oxygen sensor is kept in a second locked box under the locked oxygen generator cover. Therefore, it is not possible for unauthorized persons to open this cover.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R27/RI	*Failure of the Device to Perform its Function*	Functionality	*Mechanical and piping installation of the device by unauthorized persons*	*4*	*2*	*8*	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, the " Mechanical and piping installation of the device must be done by trained people only ," stated under the "Warnings and Precautions" heading of the User's Manual . With the ” warning, users are warned against unfavorable situations.* *The product image and details are given in the User's Manual of the device. For this reason, as long as the user manual is examined, it is not possible for the products to be wrong. The entire assembly of the oxygen generator, which is the most critical and most complex component in the system, is done in the factory, and it is sent as a whole after all tests. Therefore, the possibility of incorrect assembly is eliminated.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R28/RI	*Injury to the Caregiver*	Functionality	*Failure to pay attention to the points to be considered while maintaining the device*	*4*	*2*	*8*	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition , it should be noted that the system has been turned off, the system has been depressurized and the gas connections have been cut while the device is being maintained. ” and “ When servicing control valves, care should be taken to use only oil suitable for oxygen service. Oil, grease or other oils not designed for oxygen should not be used. Such oils can cause burning or explosion. Users are warned against unfavorable situations with ” warnings.* *A warning is attached on the filters that they should not be opened under pressure.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25

R29/RI	*Failure of the Device to Perform its Function*	Functionality	*Inappropriate Supply Air Temperature*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, the " supply air temperature of the system should not be above 40°C or below 5°C, " stated under the "Warnings and Precautions" heading of the User's Manual . With the ” warning, users are warned against unfavorable situations.* *With the PT-100 temperature sensor installed in the oxygen generator air inlet line, the system warns the user when it exceeds 40 degrees, and automatically stops the system when it exceeds 45 degrees.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R30/RI	*Damage to Device or User*	Functionality	*Not knowing what to do in case of danger*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, " In case of danger;* ○ *First aid box and fire extinguishers should be kept in an accessible place,* ○ *Personnel should be informed about the emergency plan,* ○ *Emergency stop must be activated,* *First aid measures should be taken in accordance with the emergency plan. Users are warned against unfavorable situations with ” warnings.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25
R31/RI	*Damage to the Device*	Functionality	*Operating the device with an unsuitable power supply*	4	2	8	☐ GT ☐ KT ☒ GV	*User Manuals are prepared by us in accordance with EN 1041 Standard. Prepared User Manuals are presented to users together with the device every time a device is sold. In addition, the "Device, which is stated under the "Warnings and Precautions" heading of the User's Manual , must be powered only from the electrical network with a protective grounding connection. With the ” warning, users are warned against unfavorable situations.*	4	2	8	The determined risk could not be reduced to the minimum levels to which it can be reduced. Since there are no measures to be taken, it will now be considered as a risk by us.	5	5	25

R32/RI	Unable to use device or monitor values	Functionality	The screen does not transmit the image	4	2	8	☒ GT ☒ KT ☐ GV	The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device. In addition, our device has a touch screen and other components that will enable reading of values, giving visual alarms and making selections such as mode selection. **(See:** Design File) When the production process, which is carried out by us in accordance with the PR.07 Procedure, is completed, the control process, including whether all functions work or not, is applied and recorded before the release is approved. The output of the devices that are found to be unsuitable as a result of the control is not allowed. **(See:** Production and Quality Control Procedure) In addition, all components, including the touch screen, purchased from the suppliers with whom critical supplier contracts are signed according to the NBOG 2010 Manual, are checked by us in accordance with the PR.06 Procedure after each purchase. Products that are found unsuitable during the input controls are not accepted into the warehouse.	4	one	4	The identified risk has been reduced to the minimum levels that can be reduced by the measures taken by us.	5	5	25

R33/RI	Failure of the device to function	Functionality	Inability to select on the Touch Screen	4	2	8	☒ GT ☒ KT ☐ GV	The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device. In addition, our device has a touch screen and other components that will enable reading of values, giving visual alarms and making selections such as mode selection. **(See:** Design File) When the production process, which is carried out by us in accordance with the PR.07 Procedure, is completed, the control process, including whether all functions work or not, is applied and recorded before the release is approved. The output of the devices that are found to be unsuitable as a result of the control is not allowed. **(See:** Production and Quality Control Procedure) In addition, all components, including the touch screen, purchased from the suppliers with whom critical supplier contracts are signed according to the NBOG 2010 Manual, are checked by us in accordance with the PR.06 Procedure after each purchase. Products that are found unsuitable during the input controls are not accepted into the warehouse. Finally, the software used in our device has been designed by us and the validation process has been carried out in accordance with the EN 62304 Standard. **(See:** Software Validation)	4	one	4	The identified risk has been reduced to the minimum levels that can be reduced by the measures taken by us.	5	5	25

R34/RI	Patient Injury	Functionality	Providing higher/lower pressure than the specified design pressure of the device	4	2	8	☒ GT ☒ KT ☐ GV	The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device. In addition to the compressor that will provide the pressure in our device, there are also manometers on the tanks to monitor the pressure. **(See:** Design File) The production processes of our device are carried out in accordance with the PR.07 Production and Quality Control Procedure, and the conformity of the product is ensured by the quality controls to be made during the production as well as the quality controls made by us after the production. Release approval is granted if all control results are positive. Otherwise, no device is allowed to output. **(See:** Production and Quality Control Procedure) In addition, all components, including compressors purchased from suppliers with whom critical supplier contracts have been signed, are checked by us in accordance with the PR.06 Procedure after each purchase, according to the NBOG 2010 Manual. Products found unsuitable during input controls *It can adjust 3-5 barg pressure, which is suitable for hospital devices, with the pressure regulator located at the outlet of the oxygen tank. For this reason, the operation of the system at inappropriate pressures is prevented.*	4	one	4	The identified risk has been reduced to the minimum levels that can be reduced by the measures taken by us.	5	5	25

	of the zeolite and deterioration of Oxygen purity	Functionality	*Contamination formation in zeolite stone due to the fact that CO 2 and H 2 O are not separated from the air feeding the system*	4	2	8	☒ GT ☐ KT ☐ GV	*The product design is designed and manufactured by our Design and Development Team in accordance with the Design and Development Procedure, in a way that does not impair the safety of patients, clinical conditions, health and safety of users and third parties, and protects them at a high level. In the design study, all production process requirements were included by our Design Team, considering the intended use of the product and examining the legal conditions related to our device.* *It is known that zeolites adsorb CO2 and H2O. For the adsorption process, zeolites must be of high quality and long-lasting. In this context, zeolite quality is kept at a high level by using Zeochem or Honeywell brand products. In addition, with the use of 5 micron - 1 micron - 0.01 micron filters and carbon filter (tower) and the use of +3 degrees dryer, oil and water molecules that are likely to reach the zeolites are removed from the environment with the automatic discharge valves under the filters and they are prevented from reaching the zeolites. Thus, contamination of zeolite stones is prevented. Despite all precautions, if zeolite stones are contaminated, the oxygen purity value will fall below 90% and the system will be automatically stopped by the algorithm. Therefore, it is not possible for the system to operate under high CO2 and H2O conditions.* *(See: Design File)*	4	one	4	The identified risk has been reduced to the minimum levels that can be reduced by the measures taken by us.	5	5	25

1. Risk Estimation

For each defined dangerous situation, risk estimations were made based on the experiences of the people involved in risk management, taking into account the following issues, and were recorded in the table above.

- published standards,

Scientific or technical research,

- Field data from similar medical devices currently in use, including published reported cases,
- Easy usability tests run by typical users,
- clinical evidence,
- Relevant research or simulation results or
- expert opinion

For dangerous situations where the probability of damage cannot be predicted, the possible consequences are determined using the same methods for use in risk assessment and risk control.

The risk estimation includes an analysis of the probability of harm occurring and the severity of the harm. Depending on the field of application, only certain elements of the risk estimation process may need to be considered in detail. For example, when harm is minimal, an initial hazard and consequence analysis may be sufficient, or when information or data is insufficient, a cautious estimate of the likelihood of its occurrence may be provided by the appropriately qualified and experienced Risk Management Team.

The risk management studies stated in the table above are the ones used for the purpose of " Providing the oxygen needed by the patients to the system of the health institutions ". Made for **Oxygen Production and Storage System** . In making risk assessments, first of all, **TD. RYD. The** risk management team, consisting of people whose competencies were defined in **TL.13.01 Risk Management File Preparation Instruction , took charge.**

The EN ISO 14971:2019 Standard was taken as a guide in the conduct of risk analysis. In this direction, first of all, risk management planning was carried out in accordance with the article 4.4 of the EN ISO 14971:2019 standard and the Annex-A section. In the process of determining the dangers and dangerous situations related to our products, the ANNEX-C section of the EN ISO 14971:2019 standard is used to identify the hazards that will create the risks related to our products and are recorded in the **EN 14971 APPENDIX-C Hazard Checklist** . Qualitative and quantitative features that may affect the safety of our **Oxygen Production and Storage System product, for which** risk management will be carried out later, are recorded in the **LS.13.01 Annex-A Safety and Performance Requirements Checklist** created by utilizing the APPENDIX-A sections of the ISO-TR 24971-2020 Guide . Using the Annex-C Hazard Checklist and the Annex-A Safety and Performance Requirements Checklist , the first stage of the risk assessments for our **Oxygen Production and Storage System** product was carried out and preliminary risks were determined.

2. Evaluation of Risks

Estimated risks for each dangerous situation have been evaluated in the Risk Management Report, including the following.

- Hazard description
- dangerous situations
- The impact of the risk
- The probability of the risk occurring
- the severity of the risk
- danger or dangerous situation
- Residual Risk

In the risk analysis, the dangerous situation, the dangerous situation that will cause the risk, and then the possibility and severity of this risk are evaluated in the table above.

The Matrix Method was used in the risk analysis. In this method, first of all, the probability of occurrence of the identified hazards and their impact values are determined in accordance with the "Risk Analysis Matrix Table" defined in the "Risk Management File Preparation Instruction". Then the product of effect and probability gave us the actual risk. In this direction, the measures and measures to be taken according to the magnitude of the risk obtained, or more precisely, the “Risk Hedging Method” were determined and recorded in the risk analysis table.

After the Hedging Method has been determined, the effect and probability values have been determined by re-evaluation, and the remaining risks have been determined by establishing an “impact*probability” relationship and recorded in the risk analysis table.

In the risk analysis studies, it was concluded that the necessary risk assessments were made in accordance with the EN ISO 14971:2019 Standard and ISO-TR 24971:2020 guideline. In the risk assessments, it has been seen that the risk protection methods determined against the risks are sufficient to reduce the risks to the minimum levels where they can be reduced.

3. Control of Risks

The control methods and order of importance to be applied in order to decide the acceptability of the risk by reducing the identified product risks to the minimum levels where they can be reduced are as follows;

a) Safe design and manufacturing to be applied due to the nature of the product : The precautions taken in the product design based on both the intended use of the product, the areas where it will be used and the users of the product have been defined and the risks have been evaluated.

b) The medical device itself or the protective measures during the manufacturing process : The controls and precautions taken during production and the risks have been evaluated.

c) Safety information and training for users when appropriate : Precautions taken by us for product safety and all necessary warnings regarding safety issues and issues to be followed during use Labels prepared according to EN 15223-1 Standard and usage prepared according to EN 1041 Standard are presented to the user with the manuals. In this direction, risks have been discussed and necessary definitions have been made.

Safe design and manufacture to be applied due to the nature of the product:

- In product design, studies have been carried out in line with the dangers that may occur, considering both the purpose of the product, the areas where it will be used, and the users of the product,
- With the design studies carried out, the probability of damage has been reduced,
- At the same time, the severity of the damage has been reduced and the risks have been reduced to the minimum levels where they can be reduced.

Protective measures in the medical device itself or in the manufacturing process:

- With the controls made during production and the measures taken during production, the severity of the damage has been reduced and the risks have been reduced to the minimum level where they can be reduced.

Safety information and training for users where appropriate:

- Necessary warnings against the dangers that may be encountered during use are presented with the necessary warnings both in the markings made in accordance with the EN 15223-1 Standard on the product labels and in the user manuals prepared according to the EN 1041 Standard.
- Inappropriate use, hazards that may occur, or other information that may help reduce the risk are presented to the user with labels and user manuals.

By applying all of the control methods specified according to the determined risk type, the risks are reduced to the minimum levels that can be reduced.

4. Evaluation of Residual Risk

After the implementation of the measures taken with Risk Control, new Risk Control Options are determined and implemented for the remaining risks. If a residual risk cannot be determined to be acceptable despite all applicable Risk Control Measures taken and other risk controls cannot be applied, a Risk/Benefit Analysis is performed for each remaining residual risk. For total residual risks, refer to the heading 8.Assessment of Total Residual Risk.

5. Risk/Benefit Analysis

The Risk/Benefit Analysis has been made for all the below-mentioned risks that may arise due to different potential causes and hazards in the Risk Analyzes made by us.

- Damage to the device
- User damage
- Damage to other devices in the vicinity
- Injury or Death of the User and Other Persons Around the Device
- User gas poisoning
- Damage to the device or user
- Failure to obtain oxygen from the device
- Failure of the device to produce oxygen at the desired purity
- Failure of the product to function as a result of Oxygen/Air leakage in the device
- Hearing loss of people around the device
- Patient Injury
- Failure of device function
- *Failure of the Device to Perform its Function*
- *Combustion of oxygen and explosion of the tank*
- *Fire or explosion of the device*
- *Injury to the Caregiver*
- Unable to use device or monitor values
- *of the zeolite and deterioration of Oxygen purity*
- For software-related risks (**See: Software Validation Report**)

Risk/Benefit comparisons were made in the same way for all identified risks and the following results were obtained.

providing high-purity oxygen to patients who are treated in health institutions and need oxygen has been confirmed by many scientific data used in the clinical evaluation study. In cases where **our Medical Oxygen Production and Storage System** device is not used, the disease may result in death as oxygen therapy cannot be administered to patients. In the case of using our device, the clinical benefit should occur. Meddev 2.7.1 Rev. It has been verified by the literature discussed in clinical studies conducted in accordance with the 4 Guidelines and by the Usability Study prepared in accordance with EN 62366 and EN 60601-1-6 Standards. As a result, it has been seen that our device is usable despite the above-mentioned risks.

In addition, considering the quantitative method applied in the Risk/Benefit Analysis defined in the TD.OD.RYD.TL.13.01 Risk Management File Preparation Instruction, it has been observed that the severity of the benefit to be obtained is more than 2 (two) times more than all the risk intensities that may occur.

For all identified risks, a risk/benefit analysis comparison was made in accordance with the EN 14971 Standard. In the comparison made, it was concluded that the benefit and the possibility of the benefit to be obtained for all risks are higher and the use of the product is reasonable and acceptable despite the risks determined accordingly.

6. Evaluation of New Risks Arising from Risk Control Measures

The effects of the implemented risk control measures have been reviewed in terms of whether or not the following issues occur.

- Whether new hazards or dangerous situations occur,
- Whether the estimated risks for pre-identified dangerous situations are affected by the establishment of risk control measures

As a result of the review, it has been observed that no new risk formation has been observed due to the measures taken to reduce the risk to the minimum levels where it can be reduced.

7. Integrity of Risk Control

In the risk analysis study carried out, in the step of determining the risks, all the identified hazards and risks arising from dangerous situations regarding the safety and performance of the product were considered, considering both the user, the environment in which the product is used, and the areas of use of the product. This has been confirmed by the fact that we have not encountered any risks other than the risks we have identified in the adverse event notifications and product recall examples.

All risks arising from all identified hazards and dangerous situations, and the work carried out in order to reduce the risks to the minimum levels where the risks can be reduced with the measures taken, are also controlled by the assigned persons in the risk analysis team, and the suitability of the work done is ensured.

8. Evaluation of Total Residual Risk

Damage	Hazard/Hazards	Potential Cause (Danger and Event Sequence)	Reason for not being discounted
Damage to the Device or User	➢Functionality	Incorrect use of the device	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Failure of device function	➢Functionality	The user does not know what to do even though there is a problem with the compressor during use	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.

Damage to the Device	➢Functionality	Failure to perform routine maintenance activities in a timely manner or not knowing the technical service call time(s) by the user	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Damage to the Device	➢Functionality	Failure to comply with the rules to be followed during transportation	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Failure of the Device to Perform its Function	➢Functionality	*Damage to the device*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Failure of the Device to Perform its Function	➢Functionality	*Not replacing expired components*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Harm of Patients	➢Functionality	*The tanks and piping systems used in the device are not compatible with oxygen.*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
User Harm	➢Functionality	*Not removing the exhaust gas from the device from the environment*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Damage to the Device	➢Functionality	*The pressure regulator is not installed in the system and the pressure cannot be adjusted.*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Combustion of oxygen and explosion of the tank	➢Functionality	*Smoking or an open flame source in the environment where the device is operating*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Fire or explosion of the device	➢Functionality	*Not cleaning the pipes and tanks in the system*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
User Harm	➢Functionality	*Failure to perform electrical maintenance of the device*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Failure of the Device to Perform its Function	➢Functionality	*Failure to perform electrical maintenance of the device*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.

User Harm	➢Functionality	*Touching heated parts of the device with bare hands*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Failure of the Device to Perform its Function	➢Functionality	*Mechanical and piping installation of the device by unauthorized persons*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Injury to the Caregiver	➢Functionality	*Failure to pay attention to the points to be considered while maintaining the device*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Failure of the Device to Perform its Function	➢Functionality	*Inappropriate Supply Air Temperature*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Damage to the Device or User	➢Functionality	*Not knowing what to do in case of danger*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.
Damage to the Device	➢Functionality	*Operating the device with an unsuitable power supply*	Since the determined risk cannot be reduced with the information presented to the user, and there is no other measure to be taken by us on this issue, the determined risk could not be reduced to the minimum levels that can be reduced.

RISK MANAGEMENT DECISION/CONCLUSION:

When all the studies carried out by us on behalf of risk management are examined;

- It has been observed that the Risk Control Plan has been fully implemented.
- As a result of the risk assessment, it has been verified with the "Risk/Benefit Analysis Comparison" that the remaining risks are at the minimum level where they can be reduced.
- Based on the risk analysis, risk assessment, control of the risks and the acceptability of the remaining risks as a result of the assessment, this report was created and found to be appropriate.

As a result, if our **Oxygen Production and Storage System** products are used in accordance with the user manuals and labels prepared by us, it has been decided that the products will have risks of acceptable value based on the benefit/risk analyzes made by us, and product safety and performance have been verified with these risk assessments.

Prepared	**approver**
management representative	General manager

[i]The 1st revision carried out within the scope of the 2019 revision on 01.12.2021