Certificate of Test & Calibration

ÖLÇÜM UZMANI
www.olcumuzmani.com

Test Report

Instrument:	Dew Point / Temperature Transmitter
Equipment:	MBW 373L / Auto Test System
Model Number:	PDS-D
Serial Number:	4121 8081
Date:	2021/12/09

Test Results :

Environment Temperature : 25 ºC / ±3 ºC

	Dew Point [ºC]				
Reference value	-20.4	-9.7	0.5	10.6	20.1
Calibrated value	-20.8	-9.8	-0.1	10.5	19.8
Real tolerance	-0.4	-0.1	-0.6	-0.1	-0.3
Allowed tolerance	±2 ºC	±2 ºC	±2 ºC	±2 ºC	±2 ºC

This is to certify that above mentioned products have qualified for the requirements specified in ISO 9001 (CNS 12681)

The Standards and Technical Requirements for the Products:
IEC 61298 – CE – CNS – ITS-90

Digitally signed by Cârstocea Ioan-Răzvan
Date: 2023.02.17 16:07:54 EET
Reason: MoldSign Signature
Location: Moldova

Inspector :

S. Andorfi

Certificate of Test & Calibration

ÖLÇÜM UZMANI
www.olcumuzmani.com

Test Report

Instrument:	Oxygen Measurement System
Equipment:	AVL Calibrator
Model Number:	O2S-FR-T2-18C
Serial Number:	2035
Date:	2021/11/08

Test Results :

Environment Temperature : 25 ºC / ±3 ºC

	Oxygen Content [%]				
Reference value	99.9	98	96	90	20.7
Calibrated value	99.8	97.8	96.2	90.3	20.6
Real tolerance	0.1 %	0.2 %	-0.2 %	0.3 %	0.5 %
Allowed tolerance	±0.5 %				

This is to certify that above mentioned products have qualified for the requirements specified in ISO 9001 (CNS 12681)

The Standards and Technical Requirements for the Products:
IEC 61298 – CE – CNS – ITS-90

Inspector :

S. Andorfi

INSPECTION CERTIFICATE

No.: KU-N 4122

SMC CORPORATION
1-7-14 AOYAGI, SOKA-SHI,SAITAMA-KEN,JAPAN
TEL 048 (935) 5771

CONTRACTOR MESSRS

ORDER №

№

DATE: AUG 17,2016

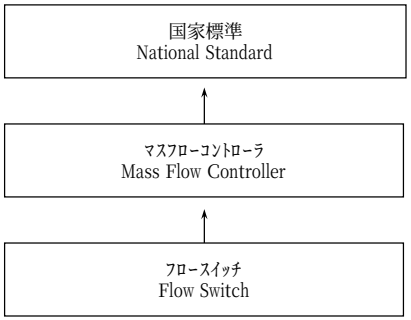
M. Miyamat

CHIEF OF INSPECTOR

品名 TITLE	フロースイッチ FLOW SWITCH	品番 MODEL №	PFMB7501-F04-E	数量 QUANTITY	1

検査項目 INSPECTION ITEM		検査方法 INSPECTION METHOD		判定基準 CRITERIA	結果 RESULT	備考 NOTE
外観 APPEARANCE		目視確認 Visual inspection		傷、汚れなきこと Be taintless with the wound.	GOOD	基準器 Standard equipment: 名称 Title :ﾏｽﾌﾛｰｺﾝﾄﾛｰﾗ Mass Flow controller 型式 Model No.:M-500SLPM-O-I-485 計器番号 Instrument No.:64342 校正書№ Calibration Certificate No. :132782
気密 AIRTIGHT		0.80MPa		$2cm^3/min$(ANR) 以下 LESS THAN	GOOD	
作動 OPERATION	押しボタン PUSH BUTTON	ボタンを押して動作確認 DC24±0.1(V) DC24±0.1(V)、Push the button and check operation.		表示されるメニュー、設定値等が変化すること Displayed menus, setting vales, etc. should change.	GOOD	
	消費電流 CURRENT CONSUMPTION	24±0.1(V) 出力ON状態 24±0.1(V) Output ON 負荷電流:無負荷 Load current: No load		55mA 以下 LESS THAN	GOOD	
	スイッチ出力 SWITCH OUTPUT	スイッチ出力、LED動作確認 Check if the analog output and the LED indication operate well		出力 ON LED点灯 ， 出力 OFF LED消灯 Output ON LED lights up 、Output OFF LED go off	GOOD	
	過電流 OVERCURRENT	過電流を流す Supply overcurrent.		エラーを検出すること An error should be detected.	GOOD	
	電源投入イニシャル表示 INITIAL DISPLAY AFTER POWER ON	仕様が正しいことを確認 Check if it matches with the specifications.		正しく表示すること The display should be correct.	GOOD	
表示精度 DISPLAY ACCURACY		検査流量 Flow rate used [L/min]	合格範囲 Criterion [L/min]	±3%F.S. 以内 WITHIN	GOOD	
		20.4	検査流量に対し、 Flow rate used, ±3%F.S.(±15L/min)			
		197.4				
		463.6				
アナログ出力精度 ANALOG OUTPUT ACCURACY		アナログ出力規格値 Specification of analog output [V]	合格範囲 Criterion [V]	±3%F.S. 以内 WITHIN	GOOD	
		1.163	アナログ出力規格値に対し、 Specification of analog output, ±3%F.S.(±0.120V)			
		2.579				
		4.709				

トレーサビリティ体系図
Traceability System Chart



I.C.S. EYECON MEDICAL S.R.L.
Piata D.Cantemir nr.1, birou nr. 1427, Chisinau, Republica Moldova
Tel: +373 22 / 99-60-10, Fax: +373 22 / 99-60-11
office@eyeconmedical.md

Act de Testare la punerea în funcțiune/ Inspectie Anuala

din 31.03.2021

1. Prin prezentul Act se confirmă faptul punerii in functiune **a:**
- **Compresor cu șurub KAESER ASD 60, serial nr. 1183-7877487 – 1 buc;**
- **Uscător prin refrigerare ACT-55, serial nr. 210006986- 1buc;**
- **Rezervor de aer zincat SICCCTECH 2000 litri serial nr. 2100576017- 1 buc;**
- **Turn cu carbune activ EVO37, serial nr. 21033321-01- 1 buc;**
- **Filtru NEA 226SMA cu purja automata- 1 buc;**
- **Filtru NEA 226SMA cu purja automata- 1 buc;**
- **Generator de oxigen POC 8300-MED, serial nr. 31.043- 1 buc;**
- **Rezervor de oxigen SICCCTECH 1000 litri serial nr. 2100537009- 1 buc;**

2. Punerea in functiune au fost executata în strictă conformitate cu termenii calitativi şi cantitativi prevăzuți de legile in vigoare ale RM, astfel prin semnatarea Actului se constata îndeplinirea integrală de către Prestator a condiţiilor de punere in functiune a Compresorului.
3. **Punerea in functiune a avut loc la data de 31.03.2021, la adresa, or. Chisinua, IMSP Cancelaria de Stat.**

4. Comisia a verificat urmatorii parametri de lucru ai statie de producere a Oxigenului Medical in Ore totale ____1____H; Ore sarcina ____1____H;
Verificari :

- Temperatura de functionare (la iesirea din bloc) :_____75___ ºC_____
- Control mod :_____DUAL _____
- Porniri motor : _____34_____
- Deschiderea supapa in sarcina : _____97_____
- Versiunea software : _____ Fluid 4.5.2_____

- Temperatura punct de roua uscător : _____3__ºC _____

Masuratori :

- Tensiunea alimentare : _____388_ V_____L1 ; _____386_ V_____L2 ; _____384__V_____L3
- Tensiunea de comanda :_____235_ V_____
- Curenti masurati dupa instalarea motorului : _____64__ A_____I1 ;_____63_ A_____I2 ;____62 A_____I3
- Temperatura din camera :_____12__ ºC _____

- Generator de oxigen : Temperatura__7.17 __ ºC ; Presiune de iesire _6.56 bar__ ; Puritate produs _94.47%_ ; Debit _7.46_ Nm3/h_.

În rezultatul efectuarii lucrarilor de Punerea în funcțiune asupra Statiei de Producere a Oxigenului nu au fost identificate abateri.

5. Din momentul predarii-primirii Prestatorul nu poartă răspundere pentru ieşirea din funcţiune a echipamenului din cauza exploatării necorespunzătoare a acesteia de către angajaţii Beneficiarului sau/si a persoanelor terţe, cărora le-a fost permis accesul la Utilaje.
6. Bineficiarul poseda toată documentaţia necesară pentru exploatarea, buna funcţionare, precum şi deservire a STATIEI DE PRODUCERE A OXIGENULUI MEDICAL.
7. Bineficiarul este informat cu regulile de exploatare a echipamentului indicate in documentatia tehnica a Compresorului.
8. **Garanţia echipamentelor enumerate la punctul (1) este de 24 (douăzeci şi patru) luni garanția generală și 24 (douăzeci și patru) luni garanția blocului de compresie conform contractului nr. MD-MHLSP-212234-GO-DIR din 27.01.2021.**
9. Actul este întocmit în 2 exemplare, cîte unul pentru fiecare semnatar.

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Obligatiuni de garantie

1.1Vanzatorul asigura reparatia de garantie gratuita in decursul termenului indicat in conditiile deservirii de garantie. Calcularea termenului deservirii de garantie se incepe din momentul semnarii Actului de Predare-Primire;
1.2 Vanzatorul este in drept sa anuleze termenul de garantie pentru dispozitivele medicale in cazul incalcarii de catre Cumparator / Beneficiar a cerintelor de exploatare si deservire a acestuia indicate in cartea de service a fiecarui echipament;
1.3 Cumparatorul se obliga sa efectueze deservirea tehnica si reparatia dispozitivelor medicale in perioada termenului de garantie exclusiv la personalul tehnic indicat de catre producator;
1.4 In momentul procurarii dispozitivelor medicale, Cumparatorul / Beneficiarul este obligat, sa faca cunostinta cu prevederile instructiunii de exploatare a dispozitivelor medicale, conditiilor de deservire pe garantie si sa se conduca strict de regulile si normele de exploatare indicate in ele;
1.5 Cumparatorul / Beneficiarul este obligat sa respecte conditiile de garantie indicate in contract, precum si conditiile de deservire indicate in manualul de service;
1.6 Cumparatorul / Beneficiarul este informat, ca producatorul si respectiv Vanzatorul este in drept in mod unilateral sa modifice conditiile de garantie si/sau conditiile de exploatare.
1.7 Perioada de garantie reprezinta perioada de timp, pe parcursul careia Vanzatorul isi asuma responsabilitatea sa inlature din contul propriu, defectele de calitate si functionare a dispozitivelor medicale, in cazul in care aceste defecte constituie defecte de productie si sunt recunoscute de catre producator. Raspunderea Vanzatorului se limiteaza la schimbul sau reparatia elementului defect sau piesei de completare la service-urile autorizate de producator;
1.8. Vanzatorul nu garanteaza ca in procesul exploatarii dispozitivelor medicale, in perioada de garantie, elementele si piesele de completare ale dispozitivelor medicale nu vor iesi din functiune;
1.9 Perioada de garantie anticoroziune constituie 36 luni;
1.10 Perioada de garantie pentru suprafata acoperita cu vopsea constituie 36 luni;
1.11 Garantia nu acopera urmatoarele cazuri:

- Distrugerea elementelor de unica folosinta si consumarea altor materiale in timpul indeplinirii deservrii tehnice planificate a diagnosticarii si a lucrarilor de calibrare (reglare);
- Uzura pieselor rezultata din utilizarea normala a echipamentului medical, invechirea fireasca si distrugerea suprafetei acoperite cu vopsea, cablajului si garniturilor in rezultatul influientei mediului inconjurator si utilizarii normale, iesirea din functiune a pieselor instalatiei in urma utilizarii consumabilelor necalitative;
- Devierile nesemnificative care nu influienteaza calitatea, caracteristicile si capacitatea de lucru a dispozitivelor medicale si a pieselor sale (de exemplu: zgomot slab sau vibratii care caracterizeaza functiunea normala a agregatelor si sistemelor sale);
- Deteriorarea in rezultatul accidentului de lucru, comportarea neglijenta, utilizarea dispozitivelor medicale in afara laboratorului, modificarea caracteristicilor si a partilor acestora, necoordonate cu Vanzatorul, defectele rezultate de supraincarcarea dispozitivului medical (chiar de scurta durata) s.a.;
- Deteriorarea dispozitivului medical cauzata de influienta externa a substantelor chimice, incediilor, catastrofelor, neglijentei, precum si a calamitatilor naturale;
- Toate lichidele de exploatare, uleiurile, materialele de ungere;
- Defectiunile rezultate din reparatia sau deservirea dispozitivelor medicale la alte service-uri, decat cele recomandate de Producator sau Vanzator;
- Lucrarile de ungere si reglaj;

1.12 Actiunea garantiei inceteaza in urmatoarele cazuri:

- Cumparatorul / Beneficiarul nu a efectuat deseervirea tehnica in service-urile autorizate;
- Dispozitivele medicale se utilizeaza fara respectarea instructiunilor si recomandarilor indicate in manualul de utilizare. Cumparatorul raspunde pentru exploatarea si intretinerea dispozitivelor medicale in conformitate cu instructiunile producatorului;
- Utilizarea dispozitivelor medicale in alte scopuri contrar destinatiilor nemijlocite;
- Exploatarea, utilizarea, intretinerea si pastrarea incorecta;
- Efectuarea modificarilor constructive fara acordul prealabil al Vanzatorului;
- Daca la dispozitivele medicale se efectueaza reparatia, demontarea (chiar si partiala) a pieselor, lucrari care au fost efectuate in afara service-urilor autorizate pentru astfel de lucrari, si/sau inclusiv daca piesele de schimb originale au fost schimbate cu piese de o alta provenienta fara acordul Vanzatorului;
- In cazul neprezentarii la solicitare pentru indeplinirea lucrarilor conform operatiilor tehnice speciale;

1.13 In cazul deservirii in baza garantiei nu se repara prejudiciul in urmatoarele cazuri:

- Refuzul cumparatorului de a efectua deservirea completa si in corespundere cu normele tehnice;
- Deservirea dispozitivelor medicale la un centru neautorizat, precum si in cazul solicitarii serviciilor de service neprevazute de garantie;
- Utilizarea de catre Cumparator/Beneficiar a pieselor neoriginale ale producatorului sau inlaturarea consecintelor reparatiei efectuate la alt service;

1.14 Cumparatorul va achita taxa pentru diagnosticare in cazul in care in urma diagnosticarii s-a stabilit ca defectiunile nu constituie obiect al garantiei acordate de Vanzator Cumparatorului;
1.15 In cazul presupunerii existentei sau a depistarii defectului la echipamentul medical, Cumparatorul este obligat imediat sa prezinte echipamentul pentru examinare (testare) colaboratorilor Vanzatorului;
1.16 In cazul depistarii defectelor colaboratorul Vanzatorului stabileste daca survenirea defectului dat este din vina producatorului si inlaturarea acestuia de catre Vanzator constituie obiectul deservirii in baza garantiei. Daca defectele depistate nu sunt acoperite de garantie, cumparatorul va achita Vanzatorului serviciile aferente depistarii si remedierii defectelor;
1.17 In cazul deservirii in baza garantiei inlaturarea defectului se efectueaza in termen de 14 zile din momentul intocmirii cererii de catre Cumparator la centrul de service al Vanzatorului cu conditia detinerii in depozit a tuturor pieselor de schimb. In cazul lipsei in depozitul Vanzatorului a pieselor de schimb, inlaturarea defectului se efectueaza timp de 14 zile din data disponibilitatii pieselor necesare. Termenul max. de livrare a pieselor de schimb este de 30 zile;
1.18 Cumparatorul este obligat:

- sa respecte toate regulile si normele de exploatare;
- sa utilizeze dispozitivele medicale in conformitate cu destinatia acestuia, tinand cont de posibilitatile si caracteristicile tehnice ale acestuia;
- sa efectueze reparatia si deservirea tehnica exclusiv in service-urile autorizate de Vinzator sau Producator.;
- sa utilizeze kiturile, consumabilele si piesele de schimb recomandate de catre producator;

In toata perioada de actiune a prezentului Act de garantie Cumparatorul nu este in drept sa vanda, sa transmita in folosinta cu titlu gratuit sau contra unei plati anumite, sa gajeze, precum si sa divizeze bunul pana la expirarea termenului de garantie fara instiintarea prealabila a Vanzatorului.

Persoanele care au semnat prezentul Act de garantie, garanteaza sub raspundere personala ca au toate imputernicirile necesare pentru aceasta, inclusiv acordul organelor de conducere ale persoanelor, pe care ii reprezinta.

	OXYGEN PRODUCTION AND STORAGE SYSTEM PRODUCTION AND QUALITY CONTROL INSTRUCTIONS			
	Document No	**Issue Date**	**Revision No**	**Revision Date**
	TL.07.06	06.04.2020	01	22.02.2021

1. PURPOSE

It has been created in order to explain how the production, packaging, labeling and quality control of our **Oxygen Production and Storage System** devices produced in our company will be made;

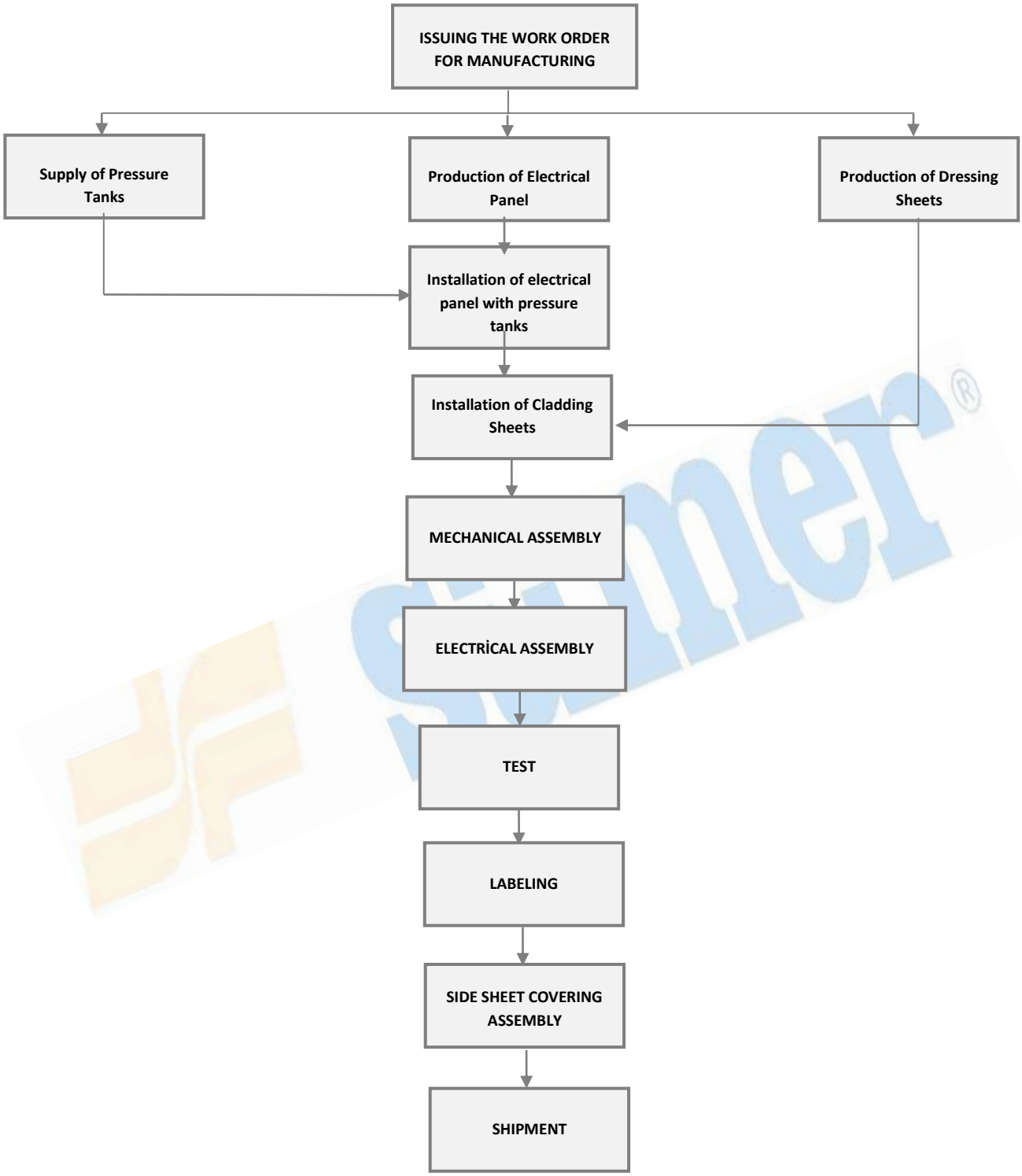
2. RESPONSIBILITY

The production responsible for the implementation of the production stages in this instruction, the quality control responsible for the implementation of the final control stages.

3. INSTRUCTION

After the notification is made to the production department with the **FR.07.01 Internal Work Order Form**, operations are carried out in accordance with the work flow chart below.

Workflow Chart:



Production of Cladding Sheets:

o The cladding sheet of the device is cut in the guillotine cutting machine in accordance with the technical drawings specified in the work order.

o The cut sheets are bent in the bending machine.

Preparation of Electrical Installation:

In our device, electrical controls are carried out with the help of the board prepared by us, and the board preparation is completed with the assembly process including the materials listed below, and the device is mounted on the device;

o The panel frame is mounted on the ready device frame.

o The panel pan, which is prepared externally, is mounted inside the panel carcass.

o Afterwards, the following items are prepared and installed on our device, respectively;

• Screen assembly,	• Valve Sockets,
• On/OFF button and Emergency Stop assembly,	• Sensors,

o The wiring systems prepared above are mounted on the panel pan in accordance with the Electrical Installation Scheme.

Making the Piping

o According to the technical drawing, the stainless pipes are cut to the appropriate length.

o Stainless pipes are mounted with Teflon tapes and a clean glove in accordance with the project.

Assembling the Prepared Pieces:

o The assembly of the product, of which all parts and sub-assembly parts are prepared, is done under this title.

o Compressor and dryer are connected to each other with pipe material and pipe diameters suitable for the project.

o Water separator and coarse filter are installed between the compressor and the dryer.

o Pipe material and pipe diameter suitable for the final project are used from the dryer.

o After the dryer, a carbon tower is assembled with a filter and a precision filter.

o Air tank is mounted on the system, sensors are connected on the air tank.

o Flow elements such as sensors, valves and pressure regulators specified in the project are mounted on the generator.

o The electrical panel is installed on the generator and its wiring is done.

o Pneumatic valve terminal is mounted on the generator and hoses are drawn to the valves.

o Oxygen tank is mounted on the system, sensors are connected on the oxygen tank.

o Check valve, particle trap filter and sterile filter and flow measuring sensor are connected to the oxygen tank outlet.

o Zeolites are filled into the generator.

o Cladding plates are attached.

o Manometers are integrated on the cladding sheet by pulling their hoses.

o When assembling the prepared parts, the following precautions should be taken against contamination that may arise from production;

❖ Gloves should be used when combining the products.

- ❖ After touching an oily place, hands should be washed and gloves should be put on again before installing the device.
- ❖ The surfaces where the pipes are left and in contact with must be cleaned.
- ❖ *When purchasing, the plugs on both ends of the pipes should not be removed. Must be removed during assembly.*[1]

Card Assembly:

When the outsourced Electronic Card reaches us, quality control procedures are carried out by our Quality Control Officer in accordance with the **PL.06.02 Semi-Product Input Control Plan.** The control results are processed into the **FR.06.07 Semi-Product Input Control Form**, and if the material is found suitable, it is taken to the production department and mounted on the product.

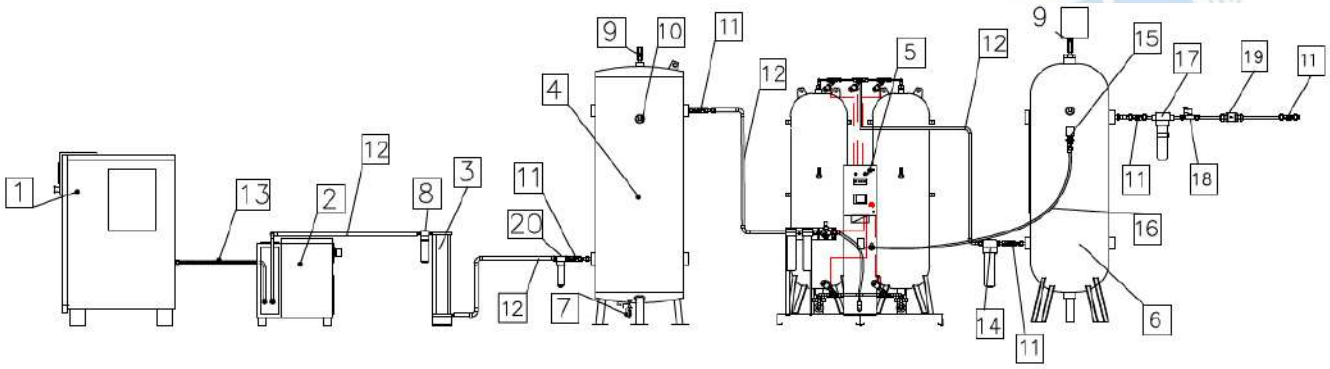


Figure 2: Product Assembly

1	Compressor	**11**	Valve
2	Dryer	**12**	Flexible Connection Hose or Stainless Pipe
3	Carbon Tower	**13**	Flexible Connection Hose
4	Air tank	**14**	Dust Filter
5	Oxygen Generator	**15**	Oxygen Pressure Sensor
6	Oxygen Tank	**16**	Flexible Connection Hose
7	Liquid Drain	**17**	Sterile Filter
8	Filter	**18**	Flow Sensor
9	Safety valve	**19**	Check Valve
10	Manometer	**20**	Filter

Installing the Software:

- ○ After the process steps up to this point are completed, our software that is validated according to the **PR.22 Software Validation Procedure** suitable for the device model is loaded.

[1] The 1st revision carried out on 22.02.2021 in line with the details of what needs to be done to prevent the contamination of the pipes

Quality Control and Sample Selection:

- The processes performed in the production processes of our device are defined below and the quality controls to be made within these steps are specified. All control results, excluding the tests, are recorded with the **FR.07.08 Oxygen Production and Storage System Production and Quality Control Form.**
  - o Cut,
  - o Twist,
  - o Security Tests,
  - o Finally, labeling and packaging

There is no special sample selection for the Quality Control processes carried out, and the controls are carried out as 100%.

Cutting and Twisting Process Controls:

It is presented in the Technical Drawings of the product to be made together with the work order opened to the production department, and in the controls to be made;

- o The part must be produced in accordance with the dimensions (at least 3 pieces) selected as reference from the technical drawing,
- o Compliance with Technical Drawings as Shape/Design,
- o There is no burr residue due to the operations carried out,
- o Surfaces are checked for scratches, dents or cracks.

Electrical Assembly Process Controls:

- o It is checked whether the panel pan is mounted inside the panel frame.
- o It is checked whether each of the items listed below is mounted in accordance with the Electrical Installation Diagram.

• Screen assembly,	• Valve Sockets,
• On/OFF button and Emergency Stop assembly,	• Sensors,

Security Tests:

The safety tests to be applied to our oxygen production and storage devices are carried out in accordance with the **TL.07.02 Safety Tests Instruction** and the control results are recorded with the **FR.07.04 Safety Tests Quality Control Form.**

Labeling and Packaging Controls:

The label prepared in accordance with the EN 15223-1 Standard defined in the technical file is fixed on the device. Label information should be as follows; (**See** Technical File Tags)

- o The product name, model and product size information should be checked and the value on the label should be entered in the "Found Result" section of the form.
- o The production date information should be checked and the value on the label should be entered in the "Found Result" section of the form.
- o Serial Number information should be checked and the value on the label should be entered in the "Found Result" section of the form.
- o Warnings for the user, if any, should be checked and the value on the label should be entered in the "Found Result" section of the form.

o The readability of all information on the label should be checked and the value on the label should be entered in the "Found Result" section of the form.

Packing the Ready-to-Ship Product:

o Our products are placed in cardboard boxes in order to avoid scratches and damage, and then they are put into wooden crates as seen in the images below and shipped.

Oxygen tanks are placed in the 1st and 3rd rows of the wooden crates, while the dryer and system are placed in the 2nd and 4th crates.[2]

Prepared	**Approver**
Management Representative	General Manager

[2] The 1st revision carried out in line with the detailing of the packaging of the ready-to-ship product on 22.02.2021