

Serving Industries for 26 years
Since 1994

## Airox Nigen

The Leaders in Adsorption Technology www.airoxnigen.com

#### Presents

# Airox Med-OX ONSITE LOW COST V.S.A / P. S. A. MEDICAL OXYGEN GAS GENERATOR

#### **UNDER LICENCE FROM AIROX NIGEN TEXAS USA**

- > Well Proven Pressure Swing Adsorption Technology
- ➤ More than 10,000 Units working successfully worldwide
- Skid-Mounted Pre-Commissioned, Ready to Use Units
- Fully Automatic Plant -Requires no Operator's Attention
- Low Generation Cost Pay Back Period, Less than a Year
- ➤ Negligible Maintenance No Hassel of changing Cylinders
- **Continuous** Purity Check Purity up to 95.% Achievable

#### The Technology (P.S.A) (PRESSURE SWING ADSORPTION)

Our Oxygen Generators operates on Pressure Swing Adsorption, commonly known as P S A Technology.

PSA Technology is based on the selective adsorption phenomena of gas molecules under pressure on the surface of highly porous and efficient adsorbent, in this case of Medical Oxygen Generation the Adsorbent is Zeolite based Molecular Sieve (Z.M.S.)

In PSA System when compressed air is passed through a adsorption tower field with Z.M.S. the molecules of Nitrogen



Carbon Di Oxide, moisture & other unwanted gases are adsorbed on surface of Z.M.S. and Oxygen which is not adsorbed by Z.M.S. comes out of adsorption tower and is collected in a surge vessel. For continuous generation of Oxygen two Adsorption towers are provided which are interconnected with Auto-change over valves controlled by PLC in the control panel. After saturation of one tower with oxygen the process automatically changes over to another tower and thus the Oxygen production is continuous.



Our systems are the best ones in industry to ensure the highest efficiency, user friendly design, Reliable Economical and Durable. Our onsite Medical Oxygen Generators are custom made and can be adjusted to give the desired nitrogen quality for your process and application.

#### Safety Features and Audio-Visual Alarms

The Oxygen Gas Generator are Skid Mounted and Pre- commissioned at our works and are fully Automatic and requires virtually no attention of the Operator. Once started it can be left-unattended. All operations take place automatically and oxygen Purity remains

very consistent. In case of any abnormality the gas Generator would trip automatically with Audio Visual Alarms for Necessary action.

#### The Technology (V.S.A) VACUUM SWING ADSROPTION

As energy and operating cost is a major concern today we have VSA technology to offer Our Oxygen Generators which operates on Vacuum Swing Adsorption, commonly known as V S A Technology.

VSA Technology is similar to PSA but operates at very low pressure of less than One Bar G and thus saves us from using of power consuming Feed Compressor as used in PSA. Instead a very efficient Oil free blower are used. While selective adsorption phenomena of gas molecules under on the surface of highly porous and efficient very special Zeolite adsorbent takes place at blower pressure, The regeneration requires to be assisted with vacuum



In VSA System when Blower air is passed through a adsorption tower field with a special Z.M.S. the molecules of Nitrogen Carbon Di Oxide , moisture & other unwanted gases are adsorbed on surface of Z.M.S. and Oxygen which is not adsorbed by Z.M.S. comes out of adsorption tower and is collected in a surge vessel. For regeneration vacuum pump is used which sucks away all the nitrogen and other gases adsorbed in the bed .For continuous generation of Oxygen eighter two Adsorption towers are provided which work in tandem alternatively or One tower is provided where in adsorption and vacuum is done alternatively

Our systems are the best ones in industry to ensure the highest efficiency, user friendly design, Reliable Economical and Durable. Our onsite Medical Oxygen Generators are custom made and can be adjusted to give the desired nitrogen quality for your process and application.



**Twin Tower VSA Unit** 



Single Tower VSA Unit

#### Safety Features and Audio-Visual Alarms



Airox MED-OX PSA or **VSA** Oxygen Gas Generator are Skid Mounted and Precommissioned at our works and are fully Automatic and requires virtually no attention of the Operator.

All System comes with 7 or 10 inch HMI Once started it can be left-unattended. All operations take place automatically and oxygen Purity remains very consistent. In case of any abnormality the gas Generator would trip automatically with Audio Visual Alarms for Necessary action.

In case of Storage Tank Getting Filled the Gas

Generator Goes to Sleep and restarts Once the pressure in storage Tank is Reduces to set Limit.

#### Airox Med-OX Oxygen Gas Booster

Airox offers Oxygen Gas Boosters along with gas filling manifolds and pigtails. Oxygen Boosters offered by us are state of art and backed by after sales services. Booster offered are from 3 m3/hr. to 100 m3/hr., Higher Capacities can also be offered





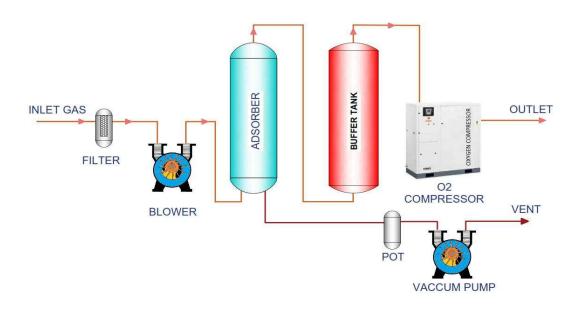
#### Airox Med-OX Systems (VSA / PSA)

A Reliable and Trusted Source of Online Oxygen Generation for Medical Use Made in India Under License from Airox Nigen Texas USA

#### SALIENT FEATURES OF AIROX MED-OX SYSTEMS

- Produces Constant Purity of 94-95% Oxygen Designed for Medical Use.
- Gas Purity Much Above Indian / European / American Pharmacopeia Regulations.
- All Airox Med–OX Systems are certified as medical equipment by ISO 13485
- All Airox Med–OX Systems comes with 26 years of existence and experience
- All Airox Med –OX Systems are CE and FDA complied
- System Designed and Backed up by 26 Years of Experience
- Compact Design with Lowest Footprint
- On-line Oxygen Purity Monitoring
- On-line Moisture (Dew Point) Monitoring (Offered as Option)
- Larger Oxygen Vessel for Peak back-up
- Complete Piping used is Sterilized Stainless Steel
- We use state of Art Change Over which comes with 5 years
   100 % replacement Guarantee with no question asked
- We Use 5th Generation Zeolite life which ensures lowest Operating Cost and Maximum Gas Generation and comes with 7 Years of Operating life.
- Our system has Off-Spec Vent valve. If the purity goes below Set Limit system does not permit impure oxygen to go into the system and automatic change over to back up cylinders happen.
- 7 (10 as an Option) Inch HMI Display System with full diagnostic and Operating history.
- Med-OX System are monitored by us 24/7 at our Gurgaon Office and on your Mobile

## AIROX MED-OX SINGLE TOWER VSA TECHNOLOGY OXYGEN GENERATION SYSTEM





SINGLE TOWER

VSA ( VACUUM SWING ADSROTION )

SAVE FLOOR SPACE

AS COMPARED TO OTHER OPTIONS



**ALL THE FETURES** 

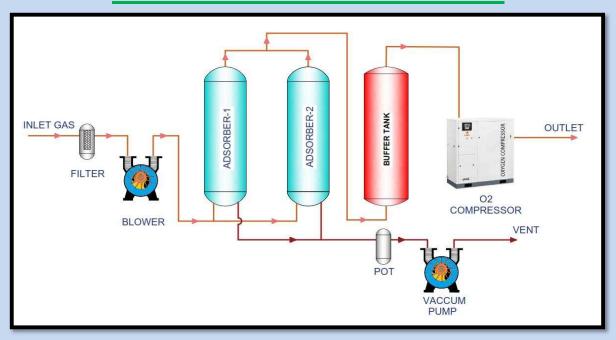


## AIROX MED-OX SINGLE TOWER VSA TECHNOLOGY OXYGEN GENERATION SYSTEM

1					
TECHNICAL DATA	AIROX MED-OX 50P	AIROX MED-OX 100P	AIROX MED-OX 200P	AIR OX M ED-OX 500P	
FLOW RATE ( LPM )	50	100	200	500	)
FLOW RATE ( Nm3/hr)	3	6	12	30	)
OXYGEN PURITY	93%+/-3% ( AT GENE	RATOR OTLET )			
OUTLET PRESSURE	OPTIONS OF 0.2 Bar G , 1.8 Bar G , 5 Bar G & 7 Bar G AVAILABLE				
BOOSTER OPTIONAL	FOR CYLINDER FILLING	FOR CYLINDER FILLING 200 & 350 Bar G WITH BOOSTERS AVAILABLE			
OPERATING TEM PERATURE	-18°C to 49°C		-18°C to 49°C	-18℃ to 49°C	-18℃ to 49°C
POWER SUPPLY	380/460/575 VAC +/- 1	10%, 50/60/60 Hz +	/- 3%, 3-Phase		
POWER REQUIRED	15 KVA	20 KVA	30 KVA	60 KVA	
POWER CONSUMPTION	4.6 KW @ 4-5 barG	8.5 KW @ 4-5 barG	16 KW @ 4-5 barG	38 KW @ 45 barG	
OUTLET CONNECTION	15 NB	15 NB	25 NB	40 NB	
SKID SIZE L x W X H ( Mtrs)	2.5 x 4 x 3	2.5 x 4 x 3	2.5 x 4 x 3	3.5 x 4 x 3	
TECHNICAL DATA	A IROX MED-OX 1KP	AIROX MED-OX 1.2KP	A IROX MED-OX 1.5KP	AIROX MED-OX 2KP	AIROX MED-OX 3KP
FLOW RATE ( LPM )	1000	1200	1500	2000	3000
FLOW RATE ( Nm3/hr)	60	110	90	120	180
OXYGEN PURITY	93% +/-3% (AT GENERATOR OTLET)				
OUTLET PRESSURE	OPTIONS OF 0.2 Bar G , 1.8 Bar G , 5 Bar G & 7 Bar G AVAILABLE				
BOOSTER OPTIONAL	FOR CYLINDER FILLING 200 & 350 Bar G WITH BOOSTERS AVAILABLE				
OPERATING TEMPERATURE	-18°C to 49°C				
POWER SUPPLY	380/460/575 VAC +/- 10%, 50/60/60 Hz +/- 3%, 3-Phase				
POWER REQUIRED	90 KVA	208 KVA	130 KVA	200 KVA	450 KVA
POWER CONSUMPTION	70 KW @ 4-5 barG	150 KW @ 4-5 barG	105 KW @ 4-5 barG	132 KW @ 4-5 barG	205 KW@4-5 barG
OUTLET CONNECTION	40 NB	50 NB	50 NB	80 NB	100 NB
SKID SIZE L x W X H (Mtrs)	4.5 x 4 x 3	6 x 2 x 3	5.5 x 4 x 3	6.5 x 4 x 3	6.5 x 4 x 3

Single Bed VSA Reduces Number of Process Valves Required.

## AIROX MED-OX / IOX TWIN TOWER VSA TECHNOLOGY OXYGEN GENERATION SYSTEM





TWIN TOWER VSA (VACUUM SWING ADSROPTION) TECHNOLOGY CAN BE OFERRED IN ANY SIZE

## AIROX MED-OX / IOX TWIN TOWER VSA TECHNOLOGY OXYGEN GENERATION SYSTEM

TECHNICAL DATA	AIROX IOX / MED-OX 200	AIROX IOX/MED-OX 500	AIROX IOX/MED-OX 1K	AIROX IOX/MED-OX 2K
FLOW RATE ( LPM )	200	500	1000	2000
FLOW RATE ( Nm3/hr)	12	30	60	120
OXYGEN PURITY	93%+/-3% (AT GENERATOR OTLET)			
OUTLET PRESSURE	OPTIONS OF 0.2 Bar G , 1.8 Bar G , 5 Bar G & 7 Bar G AVAILABLE			
BOOSTER OPTIONAL	FOR CYLINDER FILLING 200 & 350 Bar G WITH BOOSTERS AVAILABLE			
OPERATING TEMPERATURE	-18°C to 49°C	-18°C to 49°C	-18°C to 49°C	-18°C to 49°C
POWER SUPPLY	380/460/57	380/460/575 VAC +/- 10%, 50/60/60 Hz +/- 3%, 3-Phase		
POWER REQUIRED	12 KVA	25 KVA	50 KVA	100 KVA
	7.3 KW @ 1 Bar G	17 KW @ 1 Bar G	31 KW @ 1 Bar G	75 KW @ 1 Bar G
POWER CONSUMPTION	8 KW @ 4 barG	17.5 KW @ 4 barG	33 KW @ 4 barG	80 KW @ 4 barG
	8.2 KW @ 7 BarG	19 KW @ 7 BarG	37 KW @ 7 BarG	85 KW @ 7 BarG
OUTLET CONNECTION	15 NB	20 NB	25 - 40 NB	50 NB
SKID SIZE L x W X H ( Mtrs)	3 x 4 x 3	3 x 4 x 3	5 x 4 x 3	8 x 3 x 3
TECHNICAL DATA	AIROX IOX 5K	AIROX IOX 10K	AIROX IOX 20K	AIROX IOX 50K
FLOW RATE ( LPM )	5000	10000	20000	50000
FLOW RATE ( Nm3/hr)	300	600	1200	3000
OXYGEN PURITY	93%+/-3% (AT GENERATOR OTLET)			
OUTLET PRESSURE	OPTIONS OF 0.2 Bar G , 1.8 Bar G , 5 Bar G & 7 Bar G AVAILABLE			
BOOSTER OPTIONAL	FOR CYLINDER FILLING 200 & 350 Bar G WITH BOOSTERS AVAILABLE			
OPERATING TEMPERATURE	-18°C to 49°C	-18°C to 49°C	-18°C to 49°C	-18°C to 49°C
POWER SUPPLY	380/460/575 VAC +/- 10%, 50/60/60 Hz +/- 3%, 3-Phase			3-Phase
POWER REQUIRED	250 KVA	500 KVA	1000 KVA	2500 KVA
	160 KW @ 1 Bar G	300 KW @ 1 Bar G	740KW @ 1 Bar G	1500 KW @ 1 Bar G
and the second s		200 104 @ 4 50	78 KW @ 4 barG	1650 KW @ 4 barG
POWER CONSUMPTION	170 KW @ 4 barG	320 KW @ 4 barG	111111111111111111111111111111111111111	
POWER CONSUMPTION	170 KW @ 4 barG 180 KW @ 7 BarG	320 KW @ 4 barG 360 KW @ 7 BarG	830 KW @ 7 BarG	1750 KW @ 7 BarG
OUTLET CONNECTION		<u> </u>		1750 KW @ 7 BarG 500 NB

## AIROX MED-OX / IOX TWIN TOWER PSA TECHNOLOGY OXYGEN GENERATION SYSTEM





All Equipment shown in PFD are not Part of Supply unless specifically ordered

## AIROX MED-OX / IOX TWIN TOWER PSA TECHNOLOGY OXYGEN GENERATION SYSTEM

#### Each Airox MED-OX PSA System comes with

- 4 stage Air Pretreatment and filtration for particulate/bacterial Elimination
- 2 Stage Bacteria Filter for Oxygen at Final Outlet.
- Activated Carbon Adsorber Bed to remove trace oil from the downstream of air.
- Life of Activated Carbon bed 4 Years

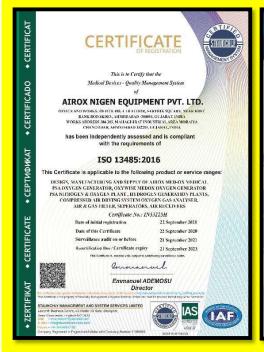
TECHNICAL DATA	AIROX MED-OX 50P	AIROX MED-OX 100P	AIROX MED-OX 200P	AIROX MED-OX 500P
FLOW RATE ( LPM )	50	100	200	500
FLOW RATE ( Nm3/hr)	3	6	12	30
OXYGEN PURITY	93%+/-3% (AT GENERATOR OTLET)			
OUTLET PRESSURE	OPTIONS OF 0.2 Bar G , 1.8 Bar G , 5 Bar G & 7 Bar G AVAILABLE			
BOOSTER OPTIONAL	FOR CYLINDER FILLING 200 & 350 Bar G WITH BOOSTERS AVAILABLE			
OPERATING TEMPERATURE	-18°C to 49°C	-18°C to 49°C	-18°C to 49°C	-18°C to 49°C
POWER SUPPLY	380/460/575 VAC +/- 10%, 50/60/60 Hz +/- 3%, 3-Phase			3-Phase
POWER REQUIRED	15 KVA	20 KVA	30 KVA	60 KVA
POWER CONSUMPTION	4.6 KW @ 4-5 barG	8.5 KW @ 4-5 barG	16 KW @ 4-5 barG	38 KW @ 4-5 barG
OUTLET CONNECTION	15 NB	15 NB	25 NB	40 NB
SKID SIZE L x W X H ( Mtrs)	2.5 x 4 x 3	2.5 x 4 x 3	2.5 x 4 x 3	3.5 x 4 x 3
TECHNICAL DATA	AIROX MED-OX 1KP	AIROX MED-OX 1.5KP	AIROX MED-OX 2KP	AIROX MED-OX 3KP
FLOW RATE ( LPM )	1000	1500	2000	3000
FLOW RATE ( Nm3/hr)	60	90	120	180
OXYGEN PURITY	93%+/-3% (AT GENERATOR OTLET)			
OUTLET PRESSURE	OPTIONS OF 0.2 Bar G , 1.8 Bar G , 5 Bar G & 7 Bar G AVAILABLE			
BOOSTER OPTIONAL	FOR CYLINDER FILLING 200 & 350 Bar G WITH BOOSTERS AVAILABLE			
OPERATING TEMPERATURE	-18°C to 49°C	-18°C to 49°C	-18°C to 49°C	-18°C to 49°C
POWER SUPPLY	380/460/575 VAC +/- 10%, 50/60/60 Hz +/- 3%, 3-Phase			
POWER REQUIRED	90 KVA	130 KVA	200 KVA	450 KVA
POWER CONSUMPTION	70 KW @ 4-5 barG	105 KW @ 4-5 barG	132 KW @ 4-5 barG	205 KW @ 4-5 barG
OUTLET CONNECTION	40 NB	50 NB	80 NB	100 NB
SKID SIZE L x W X H ( Mtrs)	4.5 x 4 x 3	5.5 x 4 x 3	6.5 x 4 x 3	6.5 x 4 x 3

#### **COMPARISON ON OFFERED TECHNOLOGIES**

	PSA Twin Tower	VSA Single Tower	VSA Twin Tower
Capital Investment	High	Lowest	Moderate
Connected Power	High	Low	Low
Power Consumption	1.1 - 1.4 kW/Nm3	0.5- 0.6 kW/Nm3	0.4 - 0.6 kW/Nm3
Floor Space	Very High	Low	Low - Moderate
Operation	Fully Automatic	Fully Automatic	Fully Automatic
Maintenance	High	Low	Low
Spares Cost	High	Low	Low
Life of Molecular Sieve	5 Years	7 Years	7 Years
Stability of Purity	Moderate	High	High
Feed Air Compressor	Required	Not Required	Not Required
Refrigerated dryer	Required	Not Required	Not Required
Oil Filters	Required	Not Required	Not Required
Compressed Air Filter	Required	Not Required	Not Required
Air Blower	Not Required	Required	Required
Vacuum Pump	Not Required	Required	Required
Adsorption Tower	Two	One	Two
PLC Operation	Yes	Yes	Yes
Change Over Valve	Eight – Ten	Two - Three	Eight
Air Receiver	Required	Not Required	Not Required
Surge Vessel	Required	Required	Required
Purge Vessel	Not Required	Required	Not Required
Vacuum Pot	Not Required	Required	Required
Gas Flow Meter	Yes	Yes	Yes
Oxygen Analyzer	Yes (Online)	Yes (Online)	Yes (Online)



### **Airox Nigen Credentials and Approvals**









Serving Industries for 26 years

Since 1994

#### AIROX NIGEN EQUIPMENTS PVT. LTD.

www.airoxnigen.com www.airoxnigen.us www.airoxnigen.ca

USA Office : Airox Nigen Projects & Equipments Inc.

17104 ANTIOCH AVE PFLUGERVILLE, TX 78660

Canada Office : Airox Nigen Projects & Equipments Ltd.

2800 Skymark Ave, Suite 200, Mississauga, ON L4W 5A6

Gurgaon Office : Airox Nigen Equipments Pvt. Ltd.

413-416, Tower B-4, SPAZE- I-TECH PARK, Sohna Rd, Sector 49,

Gurugram, Haryana 122001, India

Ahmedabad Works : Airox Nigen Equipments Pvt. Ltd.

304 & 305, Mahagujarat Industrial Area, Moraiya, Changodar,

Opp. Nova Petro, 382213 Ahmedabad, India

Call us on : USA/Canada + 1 (585)-643-1400

India + 91 99 11 88 33 00, + 91 99 49 33 00,

+ 91 124 423 0925 - 927

Email us on : sales@airoxnigen.com service@airoxnigen.com



#### **Certificate of Compliance**











ISO 9001:2001 ISO 14000:2015

OHSAS 18001:2007

ISO 13485:2016



## Certificate of Registration

This is to certify that

#### AIROX NIGEN EQUIPMENTS PVT. LTD.

AHMEDABAD OFFICE ADDRESS: 410, 4TH FLOOR, SARTHIK SQUARE, NEAR HDFC BANK, BODAKDEV, AHMEDABAD - 380054, GUJARAT, INDIA

GURUGRAM OFFICE ADDRESS: UNIT NO. 413-416, SPAZE I-TECH PARK, TOWER-B4, 4TH FLOOR, SEC 49, SOHNA ROAD, GURUGRAM-122002, HARYANA, INDIA

WORKS ADDRESS: 304-305, MAHAGUJARAT INDUSTRIAL AREA, MORAIYA-CHANGODAR, AHMEDABAD-382213, GUJARAT, INDIA has been independently assessed by QVA and is compliant with the requirement of the standard

### ISO 9001:2015

#### **Quality Management System**

For the following scope of activities

"DESIGN, MANUFACTURING, SUPPLY & INSTALLATION OF PSA/VSA NITROGEN & OXYGEN GENERATOR, HYDROGEN GAS PLANTS & GENERATORS, BIOGAS PURIFIERS & GENERATORS, COMPRESSED AIR DRYING SYSTEMS, GAS ANALYSERS, AIR & GAS FILTER SEPARATORS, PRESSURE VESSELS AND HEAT EXCHANGERS, GAS COMPRESSORS / BOOSTERS, CHILLERS"

Certificate Number: QMS-ASPL-21-201903 Verify this certificate visit at www.gaafs.us

Date of Certification $20^{TH}$  April 2021Issuance Date $20^{TH}$  April 20211st Surveillance Due $19^{TH}$  April 20222nd Surveillance Due $19^{TH}$  April 2023Re-Certificate Due $19^{TH}$  April 2024











#### **QVA Certification**

CAB Address: Maryland Avenue, SW Washington, D.C. 20202

Validity of this certificate is subject to annual surveillance audits to be done successfully

This certificate is the property of QVA Certification and shall be return immediately on request

QVA Certification is and independent Systems Products and Personal assessment Body, QVA Certification is a accredited by GAAFS.US



## Certificate of Registration

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WORKS ADDRESS: 304-305, MAHAGUJARAT INDUSTRIAL AREA, MORAIYA-CHANGODAR, AHMEDABAD-382213, GUJARAT, INDIA has been independently assessed by QVA and is compliant with the requirement of the standard

### ISO 14001:2015

#### **Environment Management System**

For the following scope of activities

"DESIGN, MANUFACTURING, SUPPLY & INSTALLATION OF PSA/VSA NITROGEN & OXYGEN GENERATOR, HYDROGEN GAS PLANTS & GENERATORS, BIOGAS PURIFIERS & GENERATORS, COMPRESSED AIR DRYING SYSTEMS, GAS ANALYSERS, AIR & GAS FILTER SEPARATORS, PRESSURE VESSELS AND HEAT EXCHANGERS, GAS COMPRESSORS / BOOSTERS, CHILLERS"

#### **Certificate Number: QVA-ASPL-21-201901**

#### To verify this certificate please visit at www.gaafs.us

20 <sup>™</sup> April 2021
20 <sup>™</sup> April 2021
19 <sup>™</sup> April 2022
19 <sup>™</sup> April 2023
19 <sup>TH</sup> April 2024













## Certificate of Registration

This is to certify that

#### AIROX NIGEN EQUIPMENTS PVT. LTD.

AHMEDABAD OFFICE ADDRESS: 410, 4TH FLOOR, SARTHIK SQUARE, NEAR HDFC BANK, BODAKDEV, AHMEDABAD - 380054, GUJARAT, INDIA

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WORKS ADDRESS: 304-305, MAHAGUJARAT INDUSTRIAL AREA, MORAIYA-CHANGODAR, AHMEDABAD-382213, GUJARAT, INDIA has been independently assessed by QVA and is compliant with the requirement of the standard

#### *ISO 45001:2018*

Occupational Health and safety Management System

For the following scope of activities

"DESIGN, MANUFACTURING, SUPPLY & INSTALLATION OF PSA/VSA NITROGEN & OXYGEN GENERATOR, HYDROGEN GAS PLANTS & GENERATORS, BIOGAS PURIFIERS & GENERATORS, COMPRESSED AIR DRYING SYSTEMS, GAS ANALYSERS, AIR & GAS FILTER SEPARATORS, PRESSURE VESSELS AND HEAT EXCHANGERS, GAS **COMPRESSORS / BOOSTERS, CHILLERS"** 

Certificate Number: QVA-ASPL-21-201902

To verify this certificate please visit at www.gaafs.us

Date of Certification Issuance Date 1st Surveillance Due 2nd Surveillance Due Re-Certificate Due

20<sup>TH</sup> April 2021

20<sup>TH</sup> April 2021 19<sup>TH</sup> April 2022

19<sup>TH</sup> April 2023

19<sup>™</sup> April 2024









QVA Certification

CAB Address: Maryland Avenue, SW Washington, D.C. 20202 Validity of this certificate is subject to annual surveillance audits to be done successfully This certificate is the property of QVA Certification and shall be return immediately on request QVA Certification is and independent Systems Products and Personal assessment Body, QVA Certification is a accredited by GAAFS.US





This is to Certify that the

Medical Devices - Quality Management System

of

#### AIROX NIGEN EQUIPMENT PVT. LTD.

OFFICE AND WORKS: OFFICE 410, 4 TH FLOOR, SARTHIK SQUARE, NEAR HDFC BANK BODAKDEV, AHMEDABAD -380054, GUJARAT, INDIA WORKS ADDRESS 304-305, MAHAGUJRAT INDUSTRIAL AREA MORAIYA CHANGODAR, AHMEDABAD 382213, GUJARAT, INDIA

has been independently assessed and is compliant with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

DESIGN, MANUFACTURING AND SUPPLY OF AIROX MED-OX MEDICAL PSA OXYGEN GENERATOR, OXYWISE MEDOX OXYGEN GENERATOR PSA NITROGEN & OXYGEN PLANT, HYDROGEN GENERATION PLANTS, COMPRESSED AIR DRYING SYSTEM OXYGEN GAS ANALYSER, AIR & GAS FILTER, SEPERATORS, AIR RECEIVERS

Certificate No.: IN53225H

Date of initial registration 22 September 2020

Date of this Certificate 22 September 2020

Surveillance audit on or before 21 September 2021

Recertification Due / Certificate expiry 21 September 2023

This Certificate is remains valid subject to satisfactory surveillance audits.





### Emmanuel ADEMOSU Director

For verification and updated information concerning the present certificate visit to http://staunchlyservices.com/search\_certified\_client.php
This Certificate is the property of Staunchly Management & System Services Limited and shall be returned immediately when demanded

#### STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED

Labrynth Business Centre, 43 Middle Hill Gate, Stockport,

Great Manchester, England-SK1 3DG
Web :- www.staunchlyservices.com
E-mail :- info@staunchlyservices.com

Phone :- +44 345 680 0199

Company Registered in England and Wales with Company Number 11488683









### Certificate of Compliance

Certificate Number: UQ-20200922014
This is to certify that

#### AIROX NIGEN EQUIPMENT PVT. LTD.

яt.

OFFICE ADDRESS: OFFICE 410,4TH FLOOR, SARTHIK SQUARE, NEAR HDFC BANK, BODAKDEV, AHMEDABAD -380054, GUJARAT, INDIA.

WORKS ADDRESS: 304-305, MAHA GUJARAT INDUSTRIAL AREA, MORAIYA, CHANGODAR, AHMEDABAD-382213, GUJARAT, INDIA

has been assessed and found to be conforming the requirements of the

## **FDA**

DESIGN, MANUFACTURING AND SUPPLY OF
AIROX MED-OX MEDICAL PSA OXYGEN GENERATOR,
OXYWISE MEDOX OXYGEN GENERATOR, PSA NITROGEN & OXYGEN
PLANT, HYDROGEN GENERATION PLANTS, COMPRESSED AIR DRYING
SYSTEM OXYGEN GAS ANALYSER, AIR & GAS FILTER, SEPERATORS,
AIR RECEIVERS.

#### This certificate is issued under the following conditions:

- It applies only to the quality system maintained in the manufacture of above referenced scope / activities.
- 2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the FDA Guidelines
- 3. The certificate validity is conditioned by positive results or surveillance audits

#### Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification22nd September 20201st Surveillance Audit Due21st September 20212nd Surveillance Audit Due21st September 2022Certificate Expiry (subject to the company maintaining its system21st September 2023



to the required standard)





Authorised Signatory

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.

71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851





### Certificate of Compliance

CE

We hereby declare that the technical files of all the items in each product group complies with the requirements of the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC Class I and Pressure Equipment Directive (PED) 2014/68/EU

Certificate No.: - CE-11386

Manufacturer : AIROX NIGEN EQUIPMENT PVT. LTD.

Address : OFFICE ADDRESS: OFFICE 410,4TH FLOOR, SARTHIK

SQUARE, NEAR HDFC BANK, BODAKDEV, AHMEDABAD -

380054, GUJARAT, INDIA.

WORKS ADDRESS: 304-305, MAHA GUJARAT INDUSTRIAL

AREA, MORAIYA, CHANGODAR, AHMEDABAD-382213,

**GUJARAT, INDIA.** 

Products : AIROX MED-OX MEDICAL PSA OXYGEN GENERATOR,

OXYWISE MEDOX OXYGEN GENERATOR,

PSA NITROGEN & OXYGEN PLANT, COMPRESSED AIR DRERS

HYDROGEN GENERATION PLANTS, GAS ANALYSER, AIR & GAS FILTER, SEPERATORS, AIR RECEIVERS.

#### Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC Class I and Pressure Equipment Directive (PED) 2014/68/EU.

#### This certificate is issued under the following conditions:

- It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
- 2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
- 3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of test report of one sample of above mentioned product. It does not imply an assessment of the whole production.

#### Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification

1st Surveillance Audit Due

2<sup>nd</sup> Surveillance Audit Due

Certificate Expiry (subject to the company maintaining its system

to the required standard)

Authorised Signatory

22nd September 2020

21st September 2021

21st September 2022

21st September 2023