Certificate of Registration

This is to certify that the Quality Management System of:

IBERGASS TECHNOLOGIES, S.L.U.

Pol.Ind. San Cristóbal. C/ Topacio 40., Valladolid 47012, Spain

applicable to:

Design and manufacture of gas generators

has been assessed and registered by NQA against the provisions of:

BS EN ISO 9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA

Managing Director

Certificate No.	50093
ISO Approval Date	10 January 2014
Reissued	23 March 2017
Valid Until:	23 March 2020
EAC Code:	18

UKAS MANAGEMENT SYSTEMS 015

Certificate of Registration

This is to certify that the Environmental Management System of:

IBERGASS TECHNOLOGIES, S.L.U.

Pol.Ind. San Cristóbal. C/ Topacio 40., Valladolid 47012, Spain

applicable to:

Design and manufacture of gas generators

has been assessed and registered by NQA against the provisions of:

ISO 14001:2015

This registration is subject to the company maintaining an environmental management system, to the above standard, which will be monitored by NQA

Managing Director

Certificate No.	71701
ISO Approval Date	23 March 2017
Valid Until:	23 March 2020
EAC Code:	18

UKAS MANAGEMENT SYSTEMS 015

Nuestra empresa tiene en tramitada Licencia **Sanitaria Previa de Funcionamiento de Instalación de Productos Sanitarios**, licencia, otorgada por la Agencia Española de Medicamentos y Productos Sanitarios.

Así mismo, tiene los **certificados de calidad ISO9001,** para el diseño, fabricación, suministro, reparación y asistencia técnica de compresores y generadores de oxígeno y nitrógeno.

Todas las máquinas y componentes de la planta cumplen con la normativa europea vigente y tiene su correspondiente **declaración CE de conformidad.**

Los generadores de oxígeno cumplen con los requisitos de las **Directiva 97/23** de equipos a presión y la **Directiva 93/42/EEC** de fabricación de equipos sanitarios y tienen el marcado CE para equipos médicos

Nuestras instalaciones de oxígeno se ajustan a las normas: **UNE-EN ISO 7396-1:2007/A1 y A2:2010**, Sistemas de canalización de gases medicinales.

El funcionamiento de nuestras plantas de oxígeno sanitario está sobradamente probado con más de 10 años de funcionamiento en hospitales privados de España.

Julio Maestro Garmilla
Director ejecutivo/C.E.O
Pol. Ind. San Cristóbal, C/ Acero 20
47012 – Valladolid (España)
Móvil: (+34) 655 977 070
correo: jmaestro@ibergass.com

Imposta di bollo assolta

Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
UFFICIO 3

DGDMF/III/P/I.5.1.e.1/2018/1084

VISTA la direttiva 93/42/CEE concernente i dispositivi medici;
HAVING REGARD *to Directive 93/42/EEC concerning medical devices;*
VISTO il Decreto Legislativo n. 46/97 e successive modifiche recante il recepimento della direttiva 93/42/CEE;
HAVING REGARD *to the Legislative Decree n. 46/97 and its following amendments implementing Directive 93/42 EEC;*
VISTA la richiesta prot. 29941-28/05/2018 presentata dalla ditta **DELTA P S.r.l.,** con sede in Via Thansau 4 – 20088 Rosate (MI), Italia, P. Iva 09011920155;
HAVING REGARD *to the request ref. 29941-28/05/2018, submitted by the Company* ***DELTA P S.r.l.*** *located in Via Thansau 4 – 20088 Rosate (MI), Italy, VAT N° 09011920155;*
CONSIDERATO che la ditta richiedente ha effettuato i versamenti richiesti dal D.M. 07 agosto 2012;
WHEREAS *the Company paid the fees required by Ministerial Decree August 7th, 2012;*
VISTI gli atti d'ufficio;
HAVING REGARD *to the official deeds:*

SI ATTESTA
IT IS ATTESTED

che la Ditta **DELTA P S.r.l.,** con sede in Via Thansau 4 – 20088 Rosate (MI), Italia, è il fabbricante e ha marcato CE come dispositivi medici, secondo le procedure previste dalla direttiva 93/42 CEE i seguenti prodotti:
that, according to Directive 93/42/EEC, the Company ***DELTA P S.r.l.*** *located in Via Thansau 4 – 20088 Rosate (MI), Italy, is the manufacturer and has marked CE as medical devices the following products:*

FAMIGLIA *FAMILY*	**RIDUTTORI DI PRESSIONE PER GAS MEDICALI** *MEDICAL GASES PRESSURE REDUCERS*
SERIE *SERIES*	**RIDUTTORI DI PRESSIONE PER GAS-TERAPIA SERIE 2270** *PRESSURE REGULATORS FOR GAS-THERAPY 2270 SERIES*
	RIDUTTORI DI PRESSIONE PER GAS MEDICALI SERIE 2232M *PRESSURE REGULATORS FOR MEDICAL GASES 2232M SERIES*
	RIDUTTORI DI PRESSIONE PER GAS MEDICALI SERIE 2210M/4420M *MEDICAL GASES PRESSURE REGULATORS 2210M/4420M SERIES*
	RIDUTTORI DI PRESSIONE PER OSSIGENO SERIE 2273 *PRESSURE REGULATORS FOR OXYGEN 2273 SERIES*

FAMIGLIA *FAMILY*	**UNITÀ TERMINALI PER LA DISTRIBUZIONE DEI GAS MEDICALI** *TERMINAL UNITS FOR COMPRESSED MEDICAL GASES AND VACUUM*
SERIE *SERIES*	**UNITÀ TERMINALI ED INNESTI A NORMA UNI 9507** *TERMINAL UNITS AND PROBES UNI 9507 STANDARD*
	UNITÀ TERMINALI ED INNESTI A NORMA AFNOR NF S 90-116

	TERMINAL UNITS AND PROBES AFNOR NF S 90-116 STANDARD
	UNITÀ TERMINALI ED INNESTI PER ARIA ED AZOTO PER STRUMENTI CHIRURGICI
	TERMINAL UNITS AND PROBES FOR AIR AND NITROGEN FOR SURGICAL TOOLS
	UNITÀ TERMINALI ED INNESTI A NORMA DIN 13 260-2
	TERMINAL UNITS AND PROBES DIN 13 260-2 STANDARD
	UNITÀ TERMINALI ED INNESTI A NORMA BS 5682
	TERMINAL UNITS AND PROBES BS 5682 STANDARD
	UNITÀ TERMINALI ED INNESTI A NORMA SS 875 24 30
	TERMINAL UNITS AND PROBES SS 875 24 30 STANDARD
FAMIGLIA *FAMILY*	**REGOLATORI DI PRESSIONE DA LINEA PER GAS MEDICALI** *IN-LINE MEDICAL GASES PRESSURE REGULATORS*
SERIE *SERIES*	**RIDUTTORI DI PRESSIONE DA LINEA PER GAS MEDICALI SERIE 2290**
	LINE PRESSURE REGULATORS FOR MEDICAL GASES 2290 SERIES
	RIDUTTORI DI PRESSIONE PER GAS MEDICALI SERIE 2250M/2251M
	MEDICAL GASES PRESSURE REGULATORS 2250M/2251M SERIES
	RIDUTTORI DI PRESSIONE DA LINEA PER GAS MEDICALI SERIE VIT38
	LINE PRESSURE REGULATORS FOR MEDICAL GASES VIT38 SERIES
FAMIGLIA *FAMILY*	**UNITÀ TERMINALI PER EVACUAZIONE GAS ANESTETICI** **TERMINAL UNITS FOR ANAESTHETIC GAS SCAVENGING SYSTEMS**
SERIE *SERIES*	**UNITÀ TERMINALI ED INNESTI PER EVACUAZIONE GAS ANESTETICI**
	TERMINAL UNITS AND PROBES FOR ANAESTETHIC GAS SCAVENGING SYSTEMS
	UNITÀ TERMINALI ATTIVE PER EVACUAZIONE GAS ANESTETICI
	ACTIVE TERMINAL UNITS FOR ANAESTETHIC GAS SCAVENGING SYSTEMS
FAMIGLIA *FAMILY*	**IMPIANTI PER GAS MEDICALI COMPRESSI E PER VUOTO** *PIPELINES FOR COMPRESSED MEDICAL GASES AND VACUUM*
SERIE *SERIES*	**IMPIANTI DI DISTRIBUZIONE DEI GAS MEDICALI COMPRESSI E PER VUOTO[IDGM]**
	PIPELINE SYSTEMS FOR COMPRESSED MEDICAL GASES AND VACUUM[MGPS]
FAMIGLIA *FAMILY*	**UMIDIFICATORI MEDICALI A GORGOGLIAMENTO PER GASTERAPIA** *MEDICAL HUMIDIFIERS FOR OXYGENTHERAPY*
SERIE *SERIES*	**UMIDIFICATORI MEDICALI A GORGOGLIAMENTO SERIE 1200**
	BUBBLE MEDICAL HUMIDIFIERS 1200 SERIES
FAMIGLIA *FAMILY*	**SERPENTINE FLESSIBILI PER GAS MEDICALI AD ALTA PRESSIONE** *HIGH PRESSURE FLEXIBLE CONNECTIONS FOR USE WITH MEDICAL GASES*
SERIE *SERIES*	**SERPENTINE FLESSIBILI PER GAS MEDICALI AD ALTA PRESSIONE SERIE 2009**
	FLEXIBLE CONNECTIONS FOR HIGH PRESSURE MEDICAL GASES 2009 SERIES
FAMIGLIA *FAMILY*	**IMPIANTI DI EVACUAZIONE DEI GAS ANESTETICI** *ANAESTHETIC GAS SCAVENGING DISPOSAL SYSTEMS*
SERIE *SERIES*	**IMPIANTI DI EVACUAZIONE DEI GAS ANESTETICI [SDEGA]**
	ANAESTHETIC GAS SCAVENGING DISPOSAL SYSTEMS [AGSS]
FAMIGLIA *FAMILY*	**RAMPE PER L'USO CON GAS MEDICINALI AD ALTA PRESSIONE** *MEDICAL GAS HIGH PRESSURE RAMPS*
SERIE *SERIES*	**RAMPE PER GAS MEDICALI AD ALTA PRESSIONE SERIE 2008M**
	RAMPS FOR HIGH PRESSURE MEDICAL GASES 2008M SERIES
FAMIGLIA *FAMILY*	**REGOLATORI DI VUOTO PER IMPIANTI DI EVACUAZIONE GAS ANESTETICI (SDEGA/AGSS)** *VACUUM REGULATORS FOR ANAESTHETIC GAS SCAVENGING SYSTEMS (AGSS)*
SERIE *SERIES*	**REGOLATORI DI VUOTO PER SDEGA/AGSS SERIE 1210**
	VACUUM REGULATORS FOR AGSS 1210 SERIES
FAMIGLIA *FAMILY*	**REGOLATORI DI VUOTO PER ASPIRAZIONE ENDOCAVITARIA** *VACUUM REGULATORS FOR ENDOCAVITARY SUCTION*
SERIE *SERIES*	**REGOLATORI DI VUOTO PER ASPIRAZIONE ENDOCAVITARIA SERIE 1212**
	VACUUM REGULATORS FOR ENDOCAVITARY SUCTION 1212 SERIES
FAMIGLIA *FAMILY*	**VASI DI RACCOLTA E VASETTI DI SICUREZZA** *COLLECTION AND SAFETY CONTAINERS*
SERIE *SERIES*	**VASI DI RACCOLTA PER ASPIRAZIONE ENDOCAVITARIA**
	COLLECTION CONTAINERS FOR ENDOCAVITARY SUCTION
	VASETTI DI SICUREZZA PER ASPIRAZIONE ENDOCAVITARIA

	SAFETY CONTAINERS FOR ENDOCAVITARY SUCTION
FAMIGLIA *FAMILY*	**FLUSSOMETRI PER GAS MEDICALI** *MEDICAL GASES FLOWMETERS*
SERIE *SERIES*	**FLUSSOMETRI PER GAS MEDICALI SERIE 2020** *MEDICAL GASES FLOWMETERS 2020 SERIES*
FAMIGLIA *FAMILY*	**CENTRALINE DI DECOMPRESSIONE DI PRIMO STADIO PER GAS MEDICALI** *FIRST STAGE DECOMPRESSION UNITS FOR MEDICAL GASES*
SERIE *SERIES*	**CENTRALINE DI DECOMPRESSIONE DI PRIMO STADIO PER GAS MEDICALI SERIE 2002M** *FIRST STAGE DECOMPRESSION UNITS FOR MEDICAL GASES 2002M SERIES*
FAMIGLIA *FAMILY*	**SISTEMI DI INTERCETTAZIONE DI AREA** *AREA SHUT-OFF SYSTEMS*
SERIE *SERIES*	**VALVOLE DI INTERCETTAZIONE DI AREA SERIE 2600N** *SHUT-OFF AREA VALVES 2600N SERIES*
FAMIGLIA *FAMILY*	**CONCENTRATORI DI OSSIGENO** *OXYGEN CONCENTRATORS*
SERIE *SERIES*	**CONCENTRATORI DI OSSIGENO SERIE OXGEN 3000** *OXYGEN CONCENTRATORS OXGEN 3000 SERIES*
FAMIGLIA *FAMILY*	**CENTRALI DI ALIMENTAZIONE CON COMPRESSORE PER ARIA MEDICINALE** *SUPPLY SYSTEMS WITH COMPRESSOR FOR MEDICAL AIR*
SERIE *SERIES*	**CENTRALI DI ALIMENTAZIONE CON COMPRESSORE PER ARIA MEDICINALE SERIE 2055M** *SUPPLY SYSTEMS WITH COMPRESSOR FOR MEDICAL AIR 2055M SERIES*
	DISPOSITIVI MEDICI DI CUI AL CERTIFICATO CE IMQ N. 1577/MDD
FAMIGLIA *FAMILY*	**DISPOSITIVI DI MONITORAGGIO E ALLARME PER IMPIANTI DI DISTRIBUZIONE DI GAS MEDICALI** *MONITORING AND ALARM DEVICES FOR MEDICAL GASES PIPELINE SYSTEMS*
SERIE *SERIES*	**ALLARMI PER IMPIANTI GAS MEDICALI SERIE AS-2025M** *ALARMS FOR MEDICAL GASES PIPELINE SYSTEMS AS-2025M SERIES*

Tali prodotti, in base all'art. 4 della citata direttiva, sono di libera circolazione e possono essere messi in commercio in Italia e in tutto il territorio dell'Unione Europea.

The above mentioned products, according to the art. 4 of Directive 93/42/EEC, can freely circulate and can be placed on the market in Italy and all over the European Union.

Questo documento è rilasciato in unico originale a richiesta del fabbricante ai fini di esportazione di dispositivi medici in **Paesi al di fuori della Unione Europea**.

This document has been issued in an unique original version upon request of the manufacturer in order to export medical devices to **Countries outside European Union**.

Non è consentita la sua riproduzione o pubblicazione su carta, stampa, supporti elettronici o siti internet.

It is not allowed any reproduction or publication of this document by paper, press, electronic base or websites.

Ne è consentita la sola esibizione o consegna alle autorità doganali o sanitarie del paese di importazione.

It is only allowed to show or to delivery it, upon request of the customs or Health Competent Authorities of the importing country.

Il Direttore dell'Ufficio
The Office Manager
Dr. Annamaria DONATO

LDL

www.imq.it

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. / *CERTIFICATE N.* 9124.DEL2

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

DELTA P SRL

VIA THANSAU 4 - 20088 ROSATE (MI)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA THANSAU 4 - 20088 ROSATE (MI)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, commercializzazione, revisione, collaudo e manutenzione/assistenza di apparecchiature e sistemi per l'utilizzo dei gas compressi medicinali, per il vuoto, per l'evacuazione dei gas anestetici e per sistemi iperbarici medicali e similari. Progettazione, costruzione, revisione, collaudo e manutenzione/assistenza di impianti per la distribuzione dei gas compressi medicinali, per il vuoto, per l'evacuazione dei gas anestetici e per sistemi iperbarici medicali e similari. Revisione, collaudo e manutenzione/assistenza tecnica di camere iperbariche medicali e similari. Progettazione, produzione, commercializzazione, revisione, collaudo e manutenzione/assistenza tecnica di concentratori di ossigeno, sistemi con concentratori di ossigeno e relativi sistemi di riempimento con booster

Design, manufacturing, trading, revision, testing and maintenance/assistance of devices and systems for compressed medicinal gases, vacuum, anaesthetic gas scavenging and medical hyperbaric systems and similar. Design, construction, revision, testing and maintenance/assistance of pipeline systems for compressed medicinal gases, vacuum, anaesthetic gas scavenging and medical hyperbaric systems and similar. Technical assistance, maintenance, revision and testing of medical hyperbaric chambers and similar. Design, production, trading, revision, testing and maintenance/technical assistance of oxygen concentrators, systems with oxygen concentrators and related filling systems with booster

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1998-05-19	2018-08-01	2021-12-14

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

IMQ

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

Organismo di Certificazione Federato CISQ
www.imq.it

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

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CERTIFICATO N. / *CERTIFICATE N.* 9124.DEL2

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

DELTA P SRL

VIA THANSAU 4 - 20088 ROSATE (MI)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA THANSAU 4 - 20088 ROSATE (MI)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, commercializzazione, revisione, collaudo e manutenzione/assistenza di apparecchiature e sistemi per l'utilizzo dei gas compressi medicinali, per il vuoto, per l'evacuazione dei gas anestetici e per sistemi iperbarici medicali e similari. Progettazione, costruzione, revisione, collaudo e manutenzione/assistenza di impianti per la distribuzione dei gas compressi medicinali, per il vuoto, per l'evacuazione dei gas anestetici e per sistemi iperbarici medicali e similari. Revisione, collaudo e manutenzione/assistenza tecnica di camere iperbariche medicali e similari. Progettazione, produzione, commercializzazione, revisione, collaudo e manutenzione/assistenza tecnica di concentratori di ossigeno, sistemi con concentratori di ossigeno e relativi sistemi di riempimento con booster

Design, manufacturing, trading, revision, testing and maintenance/assistance of devices and systems for compressed medicinal gases, vacuum, anaesthetic gas scavenging and medical hyperbaric systems and similar. Design, construction, revision, testing and maintenance/assistance of pipeline systems for compressed medicinal gases, vacuum, anaesthetic gas scavenging and medical hyperbaric systems and similar. Technical assistance, maintenance, revision and testing of medical hyperbaric chambers and similar. Design, production, trading, revision, testing and maintenance/technical assistance of oxygen concentrators, systems with oxygen concentrators and related filling systems with booster

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1998-05-19	2018-08-01	2021-12-14

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

IMQ

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

Organismo di Certificazione Federato CISQ
www.imq.it

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

BUREAU VERITAS
Certification

Certificate

Awarded to

OMEGA AIR d.o.o. Ljubljana

CESTA DOLOMITSKEGA ODREDA 10, 1000 LJUBLJANA, SLOVENIA

Bureau Veritas Certification Holding SAS – UK Branch certify that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standard detailed below

STANDARD

ISO 9001:2008

SCOPE OF CERTIFICATION

DEVELOPMENT, DESIGN, ENGENEERING SERVICES, MANUFACTURING, SALES AND SERVICE OF EQUIPMENT AND SYSTEMS FOR GAS COMPRESSING, GAS FILTRATION AND SEPARATION, CONDENSATE TREATMENT, MEASUREMENT, HVAC AND RENEWABLE ENERGY; PROVIDING SALES, REPRESENTATIVE, SERVICE AND TRAINING SERVICES.

Certification cycle start date: **16/09/2015**

Subject to the continued satisfactory operation of the organisation's Management System, this certificate expires on: **16/09/2018**

Original certification date: **16/09/2003**

Certificate number: **SL21063Q** *Version number:* **01** *Revision date:* **16/09/2015**

UKAS MANAGEMENT SYSTEMS
008

Signed on behalf of BVCH SAS UK Branch

Certification body address: 66 Prescot Street, London, E1 8HG, United Kingdom
Local office: Linhartova cesta 49a, 1000 Ljubljana, Slovenia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organization.

To check this certificate validity please call: + 386 1 47 57 670.

BUREAU VERITAS
Certification

Certifikat

prejme

OMEGA AIR d.o.o. Ljubljana

CESTA DOLOMITSKEGA ODREDA 10, 1000 LJUBLJANA, SLOVENIJA

Bureau Veritas Certification Holding SAS – UK Branch potrjuje, da je bila opravljena presoja sistema vodenja v navedeni organizaciji in da je uvedeni sistem vodenja skladen z zahtevami sledečega standarda

STANDARD

ISO 9001:2008

PODROČJE CERTIFICIRANJA

RAZVOJ, PROJEKTIRANJE, PRODAJA IN SERVIS OPREME IN SISTEMOV ZA KOMPRIMIRANJE PLINOV, FILTRACIJO IN SEPARACIJO PLINOV, OBDELAVO KONDENZATA, MERJENJE, HVAC IN OBNOVLJIVE VIRE ENERGIJE; IZVAJANJE STORITEV TRGOVINE, ZASTOPANJA, SERVISIRANJA IN IZOBRAŽEVANJA.

Datum začetka certifikacijskega cikla: **16/09/2015**

Pod pogojem, da organizacija neprekinjeno zagotavlja zadovoljivo delovanje sistema vodenja, je veljavnost tega certifikata do: **16/09/2018**

Prvotni datum odobritve: **16/09/2003**

Številka certifikata: **SL21063Q** *Izdaja:* **01** *Datum izdaje:* **16/09/2015**

UKAS MANAGEMENT SYSTEMS
008

Podpisano v imenu BVCH SAS UK Branch

Naslov certifikacijske hiše: 66 Prescot Street, London, E1 8HG, Velika Britanija
Lokalna pisarna: Linhartova cesta 49a, 1000 Ljubljana, Slovenija

Dodatna pojasnila v zvezi s področjem certificiranja ter sistemom vodenja, ki ga pokriva ta certifikat, lahko dobite pri certificirani organizaciji.

Za podrobnejše informacije o veljavnosti tega certifikata pokličite: + 386 1 47 57 670.

CERTIFICATO DI APPROVAZIONE DEL SISTEMA DI QUALITA'

CERTIFICATE OF QUALITY SYSTEM APPROVAL

N° CE-1370-PED-H1-OAI 001-15-SVN-revB

Bureau Veritas Italia SpA, agendo nell'ambito della notifica (numero dell'organismo notificato 1370), attesta che il sistema di qualità applicato dal fabbricante per la progettazione, la produzione, l'ispezione finale e le prove sull'attrezzatura a pressione identificata di seguito è stato esaminato secondo le prescrizioni del modulo H1 dell'allegato III della direttiva "Attrezzature a pressione" n. 2014/68/UE ed è conforme alle disposizioni della stessa.

Bureau Veritas Italia SpA, acting within the scope of its notification (notified body number 1370), attests that the quality system operated by the manufacturer for design, manufacturing, final product inspection and testing of the pressure equipment identified hereunder has been examined against the provisions of annex III, module H1, of the Pressure Equipment Directive n° 2014/68/EU, and found to satisfy the provisions of the directive which apply to it.

Fabbricante (Nome) / *Manufacturer (Name):* Indirizzo / *Address:*	**OMEGA AIR d.o.o., Ljubljana** **Cesta Dolomitskega odreda 10, 1000 Ljubljana, SLOVENIA**
Nome - Marchio commerciale : *Trading Name - Mark :*	OMEGA AIR
Descrizione dell'attrezzatura / *Equipment description:* Identificazione delle attrezzature (elenco in allegato ove necessario) : *Identification of equipment concerned (or list on the back or attached where necessary) :*	**Unfired pressure welded vessels, filters and separators for fluids group 1&2, designed acc. to:** - **EN13445** - **ASME Section VIII Div. 1** - **AD2000 Merkblatt**
Esistenza di un allegato al certificato *Existence of an annex to the certificate*	**See Annex**
Questo certificato scadrà il (gg/mm/aaaa): *This certificate will expire on (dd/mm/yyyy):*	**18/05/2018**

L'approvazione è valida a fronte dell'esito positivo degli audit di sorveglianza, delle visite, delle prove e delle verifiche realizzate da Bureau Veritas Italia SpA secondo le condizioni definite nel contratto stipulato tra il fabbricante e Bureau Veritas Italia SpA.

The approval is conditional upon the surveillance audits, visits, tests and verifications to be carried out by Bureau Veritas Italia Spa, as per the provisions stated in the agreement signed with the manufacturer.

Questo certificato è presunto nullo ed il fabbricante si farà esclusivo carico delle conseguenze del suo utilizzo, qualora questi non rispettasse gli impegni assunti nel sottoscrivere il contratto con particolare riferimento a: (a) applicazione del sistema di qualità approvato, (b) ispezione e test sul prodotto finale, o in assenza di cambiamenti allo stato dell'arte e, in generale, se il fabbricante non rispettasse uno qualsiasi degli obblighi imposti a suo carico dalla direttiva N° 2014/68/UE del 15 maggio 2014 così come trasposta nelle leggi nazionali applicabili.

This certificate shall be deemed to be void and the manufacturer shall alone bear any consequences pursuant to its use, where the manufacturer fails to comply with his undertakings as per the agreement in respect of (a) implementation of the approved quality system and (b) inspection and tests on the final product, or in the absence of changes in the state of the reported technical and generally where the manufacturer fails in particular to comply with any of his obligations under directive nr 2014/68/EU of 15 may 2014 as transposed in the applicable law(s).

Data dell'audit iniziale (o della sorveglianza): *Date of initial (or renewal) audit (dd/mm/yyyy):*	**17/03/2017**
Ispettore / *Surveyor:*	**Boris Hladnik**

Fatto a *Made at*	Il (gg/mm/aaaa) *On (dd/mm/yyyy)*	Approvato e Registrato in Approved and *Recorded in*	Firmato da *Signed by*	Firma autorizzata dall'Organismo Notificato No. 1370 *Signature authorised by Notified Body No. 1370*
Milano	**19/03/2017**	**ITALY**	**Zoran GLIŠIČ**	
Codice di registrazione / *Registration code*: 2017/000931/CE-1370-PED				

La presente autorizzazione è soggetta alle Condizioni Generali di Bureau Veritas Italia SpA allegate al contratto firmato dal richiedente.
This certificate is subject to the terms of Bureau Veritas Italia SpA General Conditions of Service attached to the agreement signed by the applicant.

Il presente documento non può essere riprodotto parzialmente se non con l'approvazione scritta di Bureau Veritas Italia SpA e del Cliente.
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PED – H1 - Rev. 06/2016 H1

N° CE-1370-PED-H1-OAI 001-15-SVN-revB

Elenco delle attrezzature

List of the concerned equipment

Descrizione dell'attrezzatura / *Equipment description:*

Unfired pressure welded vessels, filters and separators, category IV, for fluids group 1&2, Families designed acc. to:

1. EN13445:
- **Welded filters, types: aS2FPxxxVyyTzzz; aS2FCxxxVyyTzzz;**
- **Welded vessels, types: aS2PDxxxVyyTzzz; aS2PxxxH/VyyTzzz; aS3PRDxxxVyyTzzz;**
- **Welded separators, types: aS2SPxxxVyyTzzz; al4SPxxxVyyTzzz; al5SPxxxVyyTzzz;**

2. ASME VIII Div.1:
- **Welded separators 1A1SxxxVyyTzzz; aS2SCxxxVyyTzzz; aA4SCxxxVyyTzzz; aA5SCxxxVyyTzzz;**

3. AD2000 Merkblatt:
- **Welded vessels, types: TPxxH/Vx; TPxxH/VxTxx; TPIxxH/Vx; TPDxxVxTxx; TPDxxVx; TPRDxxVx;**
- **Welded filters, types: VFPxxVxTxx;**

Identificazione delle attrezzature (o elenco in allegato, ove necessario) /
Identification of the equipment concerned (or list on the back or attached when necessary):

1. Unfired pressure vessels, filters and separators category IV, for fluid 1&2, acc. to EN13445:
Legend: a = fluid group, b = material, xxx = (De) outside diameter (mm), yy = (P) pressure (bar), zzz = (T) temperature (°C)

1.1. Welded filters:

1.1.1 aS2FPxxxVyyTzzz:
Versions : aS2FP323V16T120, aS2FP355V16T120, aS2FP406V16T120, aS2FP508V16T120, aS2FP610V16T120, aS2FP711V16T120 ; aS2FP219V25T120, aS2FP323V25T120, aS2FP355V25T120, aS2FP406V25T120, aS2FP508V25T120, aS2FP610V25T120, aS2FP711V25T120;
Drawings No.: aS2FP219-406V16T120 rev1, aS2FP508-711V16T120 rev.1, aS2FP219-406V25T120 rev.1, aS2FP508-711V25T120 rev.1 - date 01/04/2016;
Limitations: PS = 16, 25 bar, TS min/max = -20 / +120 °C, capacity: 15 to 860 l, Fluid 1 & 2; Steel grades: P235GH, P250GH, P265GH, P280GH, P295GH (shell, ends, nozzles, flanges); Welding joint coefficient Z = 0.85 / test group 3;

1.1.2. aS2FCxxxVyyTzzz:
Versions : aS2FC273V16T120, aS2FC323V16T120, aS2FC406V16T120, aS2FC508V16T120, aS2FC610V16T120; aS2FC219V25T120, aS2FC273V25T120, aS2FC323V25T120, aS2FC406V25T120, aS2FC508V25T120, aS2FC610V25T120;
Drawings No.: aS2FC114-610V16T120 rev.1, aS2FC114-610V25T120 rev.1 - date 01/04/2016;
Limitations: PS = 16, 25 bar, TS min/max = -20 / +120 °C, capacity: 5 to 598 l, Fluid 1 & 2; Steel grades: P235GH, P250GH, P265GH, P280GH, P295GH (shell, ends, nozzles, flanges); Welding joint coefficient Z = 1.0 / test group 3;

1.2. Welded vessels:

1.2.1. aS2PDxxxVyyTzzz:
Versions : aS2PD273V16T65, aS2PD323V16T65, aS2PD355V16T65, aS2PD368V16T65, aS2PD406V16T65; aS2PD457V16T65, aS2PD508V16T65, aS2PD600V16T65, aS2PD650V16T65, aS2PD700V16T65, aS2PD800V16T65, aS2PD900V16T65, aS2PD1000V16T65; aS2PD457V13T65, aS2PD508V13T65, aS2PD600V13T65, aS2PD650V13T65, aS2PD750V13T65, aS2PD800V13T65, aS2PD900V13T65, aS2PD950V13T65; aS2PD1050V13T65, aS2PD1200V13T65, aS2PD1300V13T65, aS2PD1500V13T65;
Drawings No.: aS2PD168-406V16T65 rev.4, aS2PD457-1000V16T65 rev.1 - date 01/010/2015; aS2PD300-1500V13T65 rev.1 – date 01/04/2016;
Limitations: PS = 13, 16 bar, TS min/max = -10 / +65 °C, capacity: 35 to 4229 l, Fluid 1 & 2; Steel grades: P235GH, P250GH, P265GH, P280GH, P295GH (shell, ends, nozzles, flanges); Welding joint coefficient Z = 0.85 & 1.0 / test group 3;

1.2.2. aS2PxxxH/VyyTzzz:
Versions : aS2P350H10T50, aS2P400H10T50, aS2P480H10T50, aS2P630H10T50, aS2P750H10T50, aS2P850H10T50, aS2P950H10T50, aS2P1000H10T50, aS2P1150H10T50, aS2P1250H10T50, aS2P1400H10T50, aS2P1600H10T50, aS2P1700H10T50, aS2P2200H10T50 ; aS2P350V10T50, aS2P400V10T50, aS2P480V10T50, aS2P630V10T50, aS2P750V10T50, aS2P850V10T50, aS2P950V10T50, aS2P1000V10T50, aS2P1150V10T50, aS2P1250V10T50, aS2P1400V10T50, aS2P1600V10T50, aS2P1700V10T50, aS2P2200V10T50;
aS2P350H13T50, aS2P400H13T50, aS2P480H13T50, aS2P630H13T50, aS2P750H13T50, aS2P850H13T50, aS2P950H13T50, aS2P1000H13T50, aS2P1150H13T50, aS2P1250H13T50, aS2P1400H13T50, aS2P1600H13T50, aS2P1700H13T50, aS2P2200H13T50;
aS2P350V13T50, aS2P400V13T50, aS2P480V13T50, aS2P630V13T50, aS2P750V13T50, aS2P850V13T50, aS2P950V13T50, aS2P1000V13T50, aS2P1150V13T50, aS2P1250V13T50, aS2P1400V13T50, aS2P1600V13T50, aS2P1700V13T50, aS2P2200V13T50;
aS2P300H16T50, aS2P350H16T50, aS2P400H16T50, aS2P480H16T50, aS2P630H16T50, aS2P650H16T50, aS2P750H16T50, aS2P850H16T50, aS2P950H16T50, aS2P1000H16T50, aS2P1150H16T50, aS2P1250H16T50, aS2P1400H16T50, aS2P1600H16T50, aS2P1700H16T50, aS2P2200H16T50;
aS2P300V16T50, aS2P350V16T50, aS2P400V16T50, aS2P480V16T50, aS2P630V16T50, aS2P650V16T50, aS2P750V16T50, aS2P850V16T50, aS2P950V16T50, aS2P1000V16T50, aS2P1150V16T50, aS2P1250V16T50, aS2P1400V16T50, aS2P1600V16T50, aS2P1700V16T50, aS2P2200V16T50;
Drawings No.: aS2P193-400H10 rev.1, aS2P480-1250H10 rev.1, aS2P1400-2200H10 rev.1, aS2P193-400H13 rev.1, aS2P480-1250H13 rev.1, aS2P1400-2200H13 rev.1, aS2P193-1250V10 rev.1, aS2P1250-1400V10 rev.1, aS2P1600-2200V10 rev.1, aS2P193-1250V13 rev.1, aS2P1250-1400V13 rev.1, aS2P1600-2200V13 rev.1 - date 01/04/2016
aS2P193-400H16, aS2P480-1250H16 rev.1, aS2P1400-2200H16 rev.1, aS2P193-1250V16 rev.1, aS2P1250-1400V16 rev.1, aS2P1600-2200V16 rev.1 - date 10/02/2017
Limitations: PS = 10, 13, 16 bar, TS min/max = -10 / +50 °C, capacity: 12 to 24850 l, fluid: group 1 & 2; Steel grades: P235GH, P250GH, P265GH, P280GH, P295GH (shell, ends, nozzles, flanges); Welding joint coefficient Z = 0.85 / test group 3;

1.2.3. aS3PRDxxxVyyTzzz:
Versions : aS3PRD152V250T65;
Drawings No.: aS3PRD127-244V250T65, – date 01/12/2016;
Limitations: PS = 250 bar, TS min/max = -10 / +65 °C, capacity: 1 - 7 l, Fluid 1 & 2; Steel grades: P355NH; Welding joint coefficient Z = 1.0

1.3. Welded separators:

1.3.1. aS2SPxxxVyyTzzz :
Versions: aS2SP273V16T120, aS2SP300V16T120, aS2SP350V16T120, aS2SP480V16T120, aS2SP550V16T120, aS2SP630V16T120;
Drawing No.: aS2SP219-630V16T120 rev.1 - date 01/04/2016;
Limitations: PS = 16 bar, TS min/max = -10 / +120 °C, capacity: 23 L to 454 L, Fluid 1 & 2; Steel grades: P235GH, P250GH, P265GH, P280GH, P295GH (shell, ends, nozzles, flanges); Welding joint coefficient Z = 0.85 / test group 3;

1.3.2. al4SPxxxVyyTzzz :
Versions: al4SP350V13T120, al4SP480V13T120, al4SP550V13T120, al4SP630V13T120;
Drawing No.: al4SP219-630V13T120 - date 10/11/2016;
Limitations: PS = 13 bar, TS min/max = -10 / +120 °C, capacity: 59 L to 512 L, Fluid 1 & 2; Steel grades: 1.4301, (shell, ends, nozzles, flanges); Welding joint coefficient Z = 0.85 / test group 3;

1.3.3. al5SPxxxVyyTzzz :
Versions: al5SP350V13T120, al5SP480V13T120, al5SP550V13T120, al5SP630V13T120;
Drawing No.: al5SP219-630V13T120 - date 10/11/2016;
Limitations: PS = 13 bar, TS min/max = -10 / +120 °C, capacity: 59 L to 512 L, Fluid 1 & 2; Steel grades: 1.4404, (shell, ends, nozzles, flanges); Welding joint coefficient Z = 0.85 / test group 3;

2. Unfired pressure vessels, category IV, for fluid 1 acc. to ASME Section VIII Div. 1:

2.1. Welded separators:

2.2.1. 1A1SxxxHyyTzzz:
Version: 1A1S812H20T120;
Drawing No.: 1A1S812H20T120 rev.1 - date 29/05/2015
Limitations: PS = 20 bar, TS min/max = -10 / +120 °C, capacity: 594 l to 2037 l, Fluid 1; Steel grades: SA-516 Gr.60, SA-516 Gr.70, SA-350 Gr.LF2, SA-333 Gr.6, SA-106 Gr.B (shell, ends, nozzles, flanges, pipes); Welding joint coefficient Z = 0.85;

2.2.2. aS2SCxxxVyyTzzz:
Version: aS2SC273V16T120; aS2SC323V16T120; aS2SC406V16T120; aS2SC508V16T120;
Drawing No.: aS2SC168-508V16T120 rev.1 - date 21/02/2017
Limitations: PS = 13 bar, TS min/max = -10 / +150 °C, capacity: 35 l to 288 l, Fluid 1 & 2; Steel grades: P235GH, P265GH, P295GH, (shell, ends, nozzles, flanges, pipes); Welding joint coefficient Z = 0.85;

2.2.3. aA4SCxxxVyyTzzz:
Version: aA4SC273V13T150; aA4SC323V13T150; aA4SC406V13T150; aA4SC508V13T150;
Drawing No.: aA4SC168-508V13T150 rev.1 - date 10/11/2016
Limitations: PS = 13 bar, TS min/max = -10 / +150 °C, capacity: 35 l to 288 l, Fluid 1 & 2; Steel grades: 1.4301, (shell, ends, nozzles, flanges, pipes); Welding joint coefficient Z = 0.85;

2.2.4. aA5SCxxxVyyTzzz:
Version: aA5SC273V13T150; aA5SC323V13T150; aA5SC406V13T150; aA5SC508V13T150;
Drawing No.: aA5SC168-508V13T150 rev.1 - date 10/11/2016
Limitations: PS = 13 bar, TS min/max = -10 / +150 °C, capacity: 35 l to 288 l, Fluid 1 & 2; Steel grades: 1.4404, (shell, ends, nozzles, flanges, pipes); Welding joint coefficient Z = 0.85;

3. Unfired pressure vessels, category IV, for fluid 2 acc. to AD2000 Merkblatt:

3.1. Family steel welded pressure vessels for storage

3.1.1. TPxxH/Vx:
(Legend: mmmm = steel grade, ddd =outside diameter (mm), V = vertical or H = horizontal)

3.1.1.1. mmmmTPdddV(H)20:
Versions: S235TP480V(H)20, S355TP480V(H)20, S235TP622V(H)20, S355TP622V(H)20, S355TP750V(H)20, S355TP850V(H)20, S355TP950V(H)20, S355TP1000V(H)20, S355TP1150V(H)20, S355TP1250V(H)20, P265TP1400V(H)20, P265TP1600V(H)20, P265TP1700V(H)20, P265TP2200V(H)20;
Drawings No.: TP480-1250H20, TP1400-2200H20, TP193-1250V20, TP1250-1400V20, TP1600-2200V20, date 20/11/2012
Limitations: PS = 20 bar, TS min/max = -10/+50°C, capacity: 156 to 24542 L, fluid: group 2; Steel grades: S235/S355/P265GH (shell, ends), S235/S355/P265GH (openings), P250GH (flanges); Welding joint coefficient Z = 0.85 / 1 (for heads);

3.1.1.2. mmmmTPdddV(H)40:
Versions: S235TP350V(H)40, S355TP350V(H)40, S235TP400V(H)40, S355TP400V(H)40, S235TP480V(H)40, S355TP480V(H)40, P265TP622V(H)40, P265TP750V(H)40;
Drawings No.: TP219-750H40, TP219-750V40, date 20/11/2012;
Limitations: PS = 40 bar, TSmin/max = -10 / +50 °C, capacity: 55 to 730 L, fluid: group 2; Steel grades: S235/S355/P265GH (shell, ends), S235/S355/P265GH (openings), P250GH (flanges); Welding joint coefficient Z = 0.85 / 1 (for heads);

3.1.1.3. mmmmTPdddV(H)45:
Versions: S355TP350V(H)45, P265TP480V(H)45, P265TP750V(H)45, P265TP1000V(H)45, P265TP1250V(H)45;
Drawings No.: TP350-1250H45, TP350-1250V45, date 20/11/2012;
Limitations: PS = 45 bar, TSmin/max = -10 / +50 °C, capacity: 55 to 2799 L, fluid: group 2; Steel grades: S235/S355/P265GH (shell, ends), S235/S355/P265GH (openings), P250GH (flanges); Welding joint coefficient Z = 0.85 / 1 (for heads);

3.1.2. TPxxH/VxTxx:

3.1.2.1. mmmmTPdddV10T100:
Versions: S355TP700V10T100;
Drawings No.: TP700V10T100, date 06/02/2013
Limitations: PS = 10 bar, TSmin/max = -10 / +100 °C, capacity: 265 to 641 L, fluid: group 2; Steel grades: S335 (shell, ends), S235/P265GH (openings); Welding joint coefficient Z = 0.85 / 1 (for heads);

3.1.2.2. mmmmTPdddV16T100:
Versions: S355TP450V16T100, S355TP480V16T100, S355TP622V16T100, S355TP750V16T100;
Drawings No.: TP114-750V16T100, date 06/02/2013;
Limitations: PS = 16 bar, TSmin/max = -10 / +100 °C, capacity: 98 to 741 L, fluid: group 2; Steel grades: S335 (shell, ends), S235/P265GH (openings); Welding joint coefficient Z = 0.85 / 1 (for heads);

3.2. Family inox welded pressure vessels for storage

3.2.1. TPIxxH/Vx
(Legend: ddd =outside diameter (mm), V = vertical or H = horizontal)

3.2.1.1. TPIdddV(H)10:
Versions: TPI622V(H)10, TPI750V(H)10;
Drawings No.: TPI250-750H10, TPI250-750V10, date 20/11/2012;
Limitations: PS = 10 bar, TSmin/max = -20 / +50 °C, capacity: 275 to 742 L, fluid: group 2; Steel grades: 1.4404/1.4301 (shell, ends), 1.4404/1.4301 (openings), 1.4404/1.4301/1.4571 (flanges); Welding joint coefficient Z = 0.85 / 1 (for heads);

3.2.1.2. TPIdddV(H)16:
Versions: TPI480V(H)16, TPI622V(H)16, TPI750V(H)16;
Drawings No.: TPI250-750H16, TPI250-750V16, date 20/11/2012;
Limitations: PS = 16 bar, TSmin/max = -20 / +50 °C, capacity: 156 to 734 L, fluid: group 2; Steel grades: 1.4404/1.4301 (shell, ends), 1.4404/1.4301 (openings), 1.4404/1.4301/1.4571 (flanges); Welding joint coefficient Z = 0.85 / 1 (for heads);

3.2.1.3. TPIdddV(H)40:
Versions: TPI350V(H)40, TPI400V(H)40, TPI480V(H)40, TPI622V(H)40, TPI750V(H)40;
Drawings No.: TPI250-750H40, TPI250-750V40, date 20/11/2012;
Limitations: PS = 40 bar, TSmin/max = -20 / +50 °C, capacity: 55 to 722 L, fluid: group 2; Steel grades: 1.4404/1.4301 (shell, ends), 1.4404/1.4301 (openings), 1.4404/1.4301/1.4571 (flanges); Welding joint coefficient Z = 0.85 / 1 (for heads);

3.3. Family welded filters

3.3.1. VFPxxVxTxx:
(Legend: ddd =outside diameter (mm), V = vertical)

3.3.1.1. VFPdddV16T120:
Versions: VFP508V16T120, VFP609V16T120, VFP711V16T120;
Drawing No.: VFP508-711V16T120, date 20/12/2012;
Limitations: PS = 16 bar, TSmin/max = -10 / +120 °C, capacity: 191,8 to 668 L, fluid: group 2; Steel grades: S355 (shell, ends), P235TR2/P235GH (openings), P280GH (flanges); Welding joint coefficient Z = 0.85 / 1 (for heads);

3.4. Family steel welded pressure vessels for storage (dynamic)

3.4.1. TPDxxVxTxx:
(Legend: ddd =outside diameter (mm), V = vertical)

3.4.1.1. TPDdddV11T60:
Versions: TPD508V11T60, TPD558V11T60, TPD609V11T60, TPD650V11T60, TPD711V11T60;
Drawings No.: TPD508-711V11T60, date 06/02/2013;
Limitations: PS = 11 bar, TSmin/max = -10 / +60 °C, capacity: 175 to 651 L, fluid: group 2; Steel grades: S355 (shell, ends); Welding joint coefficient Z = 1;

3.4.2. TPDxxVx:
(Legend: mmmm = steel grade, ddd =outside diameter (mm), V = vertical)

3.4.2.1. TPDdddV30:
Versions: S355TPD350V30, S355TPD400V30, S355TPD480V30, S355TPD570V30, S355TPD630V30, S355TPD650V30, P265TPD700V30, P265TPD750V30, P265TPD800V30, P265TPD900V30, P265TPD1000V30, P265TPD1100V30;
Drawings No.: TPD350-1100V30, date 23/05/2013;
Limitations: PS = 30 bar, TSmin/max = -10 / +50 °C, capacity: 81 to 2207 L, fluid: group 2; Steel grades: S355/P265 (shell, ends); Welding joint coefficient Z = 1;

3.4.2.2. TPDdddV40:
Versions: S355TPD480V40, P265TPD622V40, P265TPD650V40, P265TPD700V40, P265TPD750V40, P265TPD800V40, P265TPD900V40, P265TPD1000V40, P265TPD1100V40;
Drawings No.: TPD480-1100V40, date 06/02/2013;
Limitations: PS = 40 bar, TSmin/max = -10 / +50 °C, capacity: 161 to 2193 L, fluid: group 2; Steel grades: S355/P265 (shell, ends), P235 (openings), P250GH (flanges); Welding joint coefficient Z = 1;

3.4.3. TPRDxxVx:
(Legend: ddd =outside diameter (mm), V = vertical)

3.4.3.1. TPRDdddV30:
Versions: TPRD273V30, TPRD323V30, TPRD406V30;
Drawings No.: TPRD133-406V30, date 23/05/2013;
Limitations: PS = 30 bar, TSmin/max = -10 / +50 °C, capacity: 26 to 234 L, fluid: group 2; Steel grades: P235/S355 (shell, ends); Welding joint coefficient Z = 1;

3.4.3.2. TPRDdddV40:
Versions: TPRD273V40, TPRD323V40, TPRD406V40;
Drawings No.: TPRD133-406V40, date 06/02/2013;
Limitations: PS = 40 bar, TSmin/max = -10 / +50 °C, capacity: 26 to 234 L, fluid: group 2; Steel grades: P235/S355 (shell, ends); Welding joint coefficient Z = 1;

Elenco delle parti rilevanti della documentazione tecnica
List of the relevant parts of the technical documentation

Nell'esecuzione dell'attività finalizzata ad emissione del presente certificato, Bureau Veritas Italia SpA si è riferita al dossier tecnico del fabbricante di seguito identificato */ For the activity carried out for the issuance of the present certificate, Bureau Veritas Italia SpA held as reference the following manufacturer's Technical book* : **PED EN 2014_09_01 rev 5.**

DOCUMENTAZIONE E INFORMAZIONE PREPARATA O PRODOTTA DAL FABBRICANTE */ DOCUMENTS AND INFORMATION PREPARED OR PRODUCED BY THE MANUFACTURER*	**RIFERIMENTI DEI DOCUMENTI DEL FABBRICANTE VISIONATI** */ REFERENCE OF MANUFACTURER's DOCUMENT REVIEWED*
Dettagli dell'insieme / Details of assembly	Chap. 05
Fogli di calcolo / Calculation data sheet	Chap. 04
Specifica di progetto / Design specification	Chap. 04/02
Qualifiche di procedimento delle giunzioni permanenti / Qualification of welding and other processes (for permanent assembly)	Chap. 06, 07, 09
Disegni (principali e di dettaglio) Drawings (main and detailed)	Chap. 05
Analisi dei rischi / Analysis of hazards	Chap. 03
Istruzioni operative / Operating instructions	Chap. 10
Dichiarazione di conformità (tipica) Typical form of declaration of conformity	Chap. 11
Piano di ispezione e controllo Inspection plan (including witness points and hold points)	Chap. 12
Qualifiche degli operatori incaricati della realizzazione delle giunzioni permanenti Qualification of welders and other operators (for permanent joints)	Chap. 09
Disegno della targa dati o marcatura Drawing of data plate or marking	Chap. 05 (each drawing)

La presente revisione sostituisce il precedente certificate: CE-1370-PED-H1-OAI 001-15-SVN-revA
This revision supersedes certificate:

Motivo della revisione/*Reason of revision:* Added new welded vessels (types: aSbPxxxH/V16Tzzz; aSbPRDxxxVyyTzzz) and welded separators: (types: aIbSPxxxVyyTzzz; aSbSCxxxVyyTzzz; aAbSCxxxVyyTzzz).

PED – H1 - Rev. 06/2016 H1D

BOLIVIA
MINISTERIO DE SALUD Y DEPORTES

AGEMED
AGENCIA ESTATAL DE MEDICAMENTOS Y TECNOLOGÍAS EN SALUD

RESOLUCIÓN ADMINISTRATIVA N° A/055
La Paz, 13 de abril de 2021

VISTOS Y CONSIDERANDO:

Que el Articulo 41 de la Constitución Política del Estado señala que el Estado garantizará el acceso de la Población a los Medicamentos, la Ley Nº 1737 de 17 de diciembre de 1996, Decreto Supremo 25235 de 30 de noviembre de 1998, y Decreto Supremo N° 2905 de 21 de septiembre de 2016 en su Artículo 7 Inciso a) señala que la AGEMED, entre otras funciones tiene la de emitir licencias y autorizaciones previas de importación, apertura de empresas, cambios de razón social, certificaciones de buenas prácticas de manufactura o almacenamiento en el ámbito de regulación y fiscalización de medicamentos y tecnologías en salud, mediante Resoluciones Administrativas.

Que, mediante Informe Técnico **MSyD/AGEMED/AUMyT/AAVyC/IT/98/2021** de 13 de abril de 2021, el Departamento de Vigilancia y Control de la AGEMED acredita que la empresa sociedad de responsabilidad limitada **IBERGASS TECHNOLOGIES S.R.L.,** ha dado cumplimiento a todos los requisitos exigidos por la Ley, por lo que esa área considera procedente la solicitud de apertura de empresa.

Que, mediante **PROVEIDO AGEMED Nº 055/2021** de abril 13 de 2021 e Informe Legal **MSyD/AGEMED/ADAJ/IL/268/2021,** de 13 de abril de 2021, emitido por la División de Asuntos Jurídicos, manifiesta que la solicitud de apertura de la empresa sociedad de responsabilidad limitada **IBERGASS TECHNOLOGIES S.R.L.,** no vulnera ninguna norma jurídica vigente.

POR TANTO: El Director General Ejecutivo de la Agencia Estatal de Medicamentos y Tecnologías en Salud – AGEMED en uso de las facultades y atribuciones que le confiere el Decreto Supremo Nº 2905 de 21 de septiembre de 2016.

RESUELVE:

ARTÍCULO PRIMERO. Se autoriza la apertura de la empresa sociedad de responsabilidad limitada bajo la razón social **IBERGASS TECHNOLOGIES S.R.L.,** con la actividad exclusiva declarada de **IMPORTADORA DE DISPOSITIVOS MEDICOS,** a nivel nacional.

ARTÍCULO SEGUNDO. Se constituye domicilio legal en la ciudad de La Paz del departamento de La Paz, del Estado Plurinacional de Bolivia.

ARTÍCULO TERCERO. La empresa **IBERGASS TECHNOLOGIES S.R.L.,** debe cumplir con la regulación farmacéutica establecida en las normas legales vigentes.

Regístrese, comuníquese, cúmplase y archívese.

V°B°
JEFE DIV. DE ASUNTOS JURIDICOS
Abg. Benjamin D. Herrera S.

Dr. [illegible]
DIRECTOR GENERAL EJECUTIVO
AGENCIA ESTATAL DE MEDICAMENTOS Y TECNOLOGÍAS EN SALUD

MINISTERIO DE SALUD
AGENCIA ESTATAL DE MEDICAMENTOS Y TECNOLOGIAS EN SALUD
La Paz - Bolivia

Calle Capitán Ravelo N°2199 - Zona Sopocachi (Entre, Fernando Guachalla y Rosendo Gutiérrez) - www.agemed.gob.bo - Telf. 2440122

Certificado Nacional de Unidades Productivas

Ministerio de Desarrollo Productivo y Economía Plural

PRO BOLIVIA, en cumplimiento al D.S.29727 y verificados los requisitos establecidos segun reglamento aprobado mediante Resolución Ministerial Nº 143. 2017 confiere el presente certificado a:

NOMBRE O RAZÓN SOCIAL:	**ÌBERGASS TECHNOLOGIES S.R.L.**
REPRESENTANTE LEGAL:	PINTO MACEDO NELSON EDWIN
CATEGORIA:	**MICRO - EMPRESA**
RUBRO PRINCIPAL:	**REPARACIÓN E INSTALACIÓN DE MAQUINARIA Y EQUIPO**
ACTIVIDAD PRINCIPAL:	REPARACIÓN DE PRODUCTOS ELABORADOS DE METAL, MAQUINARIA Y EQUIPO
N° NIT / CI:	392959027
DEPARTAMENTO:	LA PAZ
MUNICIPIO:	NUESTRA SEÑORA DE LA PAZ
DOMICILIO:	CALLE LUIS CRESPO NRO. 2256
FECHA DE EMISIÓN:	10/05/2021
VIGENCIA:	10/05/2022

Nro. 24153-E

BASE LEGAL: D.S.181, ART.31

Certificado Nacional de Unidades Productivas

CATEGORIA: MICRO - EMPRESA
RUBRO PRINCIPAL: REPARACIÓN E INSTALACIÓN DE MAQUINARIA Y EQUIPO
N° NIT: 392959027
DEPARTAMENTO: LA PAZ
MUNICIPIO: NUESTRA SEÑORA DE LA PAZ
DIRECCIÓN: CALLE LUIS CRESPO NRO. 2256

Ministerio de Desarrollo Productivo y Economía Plural

Certificado Nacional de Unidades Productivas

Nro: 24153-E
NOMBRE O RAZÓN SOCIAL: ÌBERGASS TECHNOLOGIES S.R.L.
REPRESENTANTE LEGAL: PINTO MACEDO NELSON EDWIN
EMISION: 10/05/2021
VIGENCIA: 10/05/2022

Ministerio de Desarrollo Productivo y Economía Plural