



Reg. Numero /
Reg. Number MED 9809

Primo rilascio /
First issue date 1998-06-11

Scadenza /
Valid until 2023-05-26

Revisione /
Revision 13

Valido da /
Valid from 2018-05-26

Ultima modifica /
Last change date 2019-01-21

Pagina / Page 1 di / of 3

Certificato CE del Sistema di Garanzia della Qualità *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

SIARE ENGINEERING INTERNATIONAL GROUP S.r.l.

Sede Legale e Operativa / Registered and Operational Headquarter:

Via Giulio Pastore, 18
40053 Valsamoggia - Loc. Crespellano, BO - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Apparecchiature ed accessori per assistenza e controllo della ventilazione polmonare e l'anestesia / *Equipment and accessories for assistance and control of lung ventilation and anaesthesia*

Sistema per calcolo e registrazione del bilancio idrico del paziente /

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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www.kiwacermet.it

Rif. rapporto di audit/ *Ref. audit report:* 10/07/2018

Chief Operating Officer
Giampiero Belcredi



Organismo Notificato n. 0476
Notified Body nr. 0476



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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Apparecchiature ed accessori per assistenza e controllo della ventilazione polmonare e l'anestesia /
Equipment and accessories for assistance and control of lung ventilation and anaesthesia

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1102

Marca / Brandname:

SIARE

Modello / Model:

Moduli anestesia: AM 5000/3 (versione con 3 gas – 3 flussimetri / model with 3 gases – 3 rotameters)

Modello / Model:

Monitor parametri vitali: David transport; D-16

Modello / Model:

Monitor parametri vitali: Neptune 12"; Neptune 15"; Neptune 12" TS

Modello / Model:

Unità di anestesia: MORPHEUS E

Modello / Model:

Unità di anestesia: MORPHEUS LT

Modello / Model:

Unità di anestesia: MORPHEUS M

Modello / Model:

Ventilatori Polmonari: SIARETRON 1000 IPER; SIARETRON 4000; FALCO 101; FALCO 202; FALCO 202 EVO; PULSAR; SIRIO S2/T; SIRIO BABY 200; POLAR 1; POLAR 2; CAP700

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Tipologia / Medical Devices:

Sistema per calcolo e registrazione del bilancio idrico del paziente

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1301, MDS 7010

Marca / Brandname:

SIARE

Modello / Model:

IDROBUS

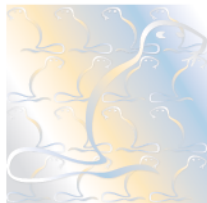
La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

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Reg. Number	18689 - M	Valid From	2021-05-27
First issue date	1997-09-23	Last change date	2021-05-27
Valid until	2024-06-01		

Previous expiry date

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

**SIARE ENGINEERING INTERNATIONAL
GROUP S.r.l. unipersonale**

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design and manufacture of equipment and accessories for assistance and control of pulmonary ventilation and anaesthesia, for operating room, emergency room, intensive care and home care; systems for calculation and recording of patient fluid balance. Marketing of accessories for assistance and control of pulmonary ventilation and anaesthesia.

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

The date of issuance of this certificate is the date of first issue by another accredited body
This certificate is composed of 1 page.

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CERMET

**SIARE ENGINEERING INTERNATIONAL
GROUP S.r.l. unipersonale**

Registered Headquarters

- Via Giulio Pastore, 18 Località Crespellano 40053 Valsamoggia (BO) Italia

Certified Sites

- Via Giulio Pastore, 18 Località Crespellano 40053 Valsamoggia (BO) Italia



SGQ N° 007A

FALCO 202 EVO

10" Portable intensive care ventilator

Oxygen driven ventilator with built-in turbine
for adults, children and new-born's

- Touch Screen -

Code: 980104

Rev. 11 - 21/02/2022



GENERAL DATA

FALCO 202 EVO 10" electronic lung ventilator is equipped with turbine and with a TFT 10,4" colour monitor touch screen displaying the curves of pressure, flow, volume, the loops of breathing parameters, the trends and the ventilation parameters.

FALCO 202 EVO 10" lung ventilator is suitable for ventilation of adult, paediatric and neonatal patients. FALCO 202 EVO 10" lung ventilator is equipped with a flow generation system by turbine with separate cooling system granting higher quality and safety standards in patient ventilation.

FALCO 202 EVO 10" is equipped with a flow and pressure trigger, it provides the most advanced volume-controlled ventilation modalities VC/VAC, VC/VAC-BABY, pressure-controlled ventilation modalities APCV (BILEVEL ST), APCV-TV, SIMV by Volume and by Pressure, Pressure supported modalities PSV (BILEVEL S), PSV-TV, CPAP, APRV, SIGH, Non-Invasive Ventilation (NIV APCV - NIV PSV), Drug Nebulizer and Manual Ventilation (MAN).

FALCO 202 EVO 10" is supplied with back up long-lasting batteries and its software can be updated for new modes and last generation ventilation strategies.

NORMS



The lung ventilator is conform to the essential requirements and it is realized according to the references of the Annex II of 93/42/EEC Medical Devices Directive.

Class and type according to EN 60601-1

Class I Type B

National classification of medical devices

Z1203010504

Class according to 93/42 EEC Directive

Class IIb, Rule 9, Type: Active according to MDD 93/42 EEC Annex IX

Electromagnetic compatibility (EMC)

EN 60601-1-2: 2015 and following

Norms	DIR. 93/42/EEC (2007); EN 60601-1:2006/ A1:2013; EN 60601-1-2:2015; IEC 60601-1-6:2013; EN 60601-1-8:2007 / A11:2017; EN 60601-2-12:2006; ISO 80601-2-12:2011; EN60601-1-11:2015; EN 62304:2006/AC:2008; EN ISO 4135:2001; DIR. 2011/65/CE; D. Lgs 49/2014; EN ISO 14971:2012, EN 1789:2007+A2:2014						
File number reference	2164108						
Unique Device Identification (UDI) number	0	80	3373726	1	2	2	4
Basic-UDI-DI							

ENVIRONMENTAL CONDITIONS

Operating	Relative humidity: 30 - 95% non-condensing Temperature: from -10 to +40°C
Storage	Relative humidity: < 95% Temperature: from -25 to +70°C

TECHNICAL DATA

Dimensions (W x H x D)	290 x 245 x 215 mm
Weight	5,5 Kg
Electric power supply	100 - 240Vac / 50 - 60Hz
<i>Power</i>	Max 60 VA
<i>External power supply (low voltage)</i>	12 Vdc / 7 A
<i>Internal battery</i>	Battery NiMh 12Vdc - 4.2 Ah
<i>Internal battery operation</i>	Max 4 hours
<i>Battery re-charging time</i>	About 10 hours
External electric connections	- RJ connector for O2 cell connection - RJ connector for Flow sensor connection
<i>Electric external connections (optional)</i>	- RS232 for CO2 module - USB 1 (connector for CPU programming) - USB 2 (connector for transfer patient data, events, trends)
Patient connections	Male conic connectors 22 mm / Female of 15 mm (according to EN ISO 5356-1:2015 norm)
<i>Overall circuit specifications - Resistance</i>	Adult patient circuit (22 mm I.D., 60 l / min flow): - Inspiratory branch: 0.13 cm H₂O / 60 l / min - Expiratory branch: 0.13 cm H₂O / 60 l / min
<i>Overall Circuit Specifications -Compliance</i>	Adult patient circuit (I.D. 22 mm): 3.85 ml / cm H ₂ O
Supply pressure (O₂)	- Low pressure (max 15 l/min) - High pressure 280 kPa - 600 kPa / 2.8 - 6 bar / 40 - 86 psi

Min flow requested (O₂) 80 l/min

IP degree of protection

IP21

The **first number** indicates the degree of protection against the penetration of solid foreign bodies.

2	protected against solid bodies greater than 12 mm in diameter
1	protected against vertical drops of water

The **second number** indicates the degree of protection against liquid penetration.

Sound pressure level measurements

Operating mode	Maximum sound measured from operator's normal position [dBA] / [dBC]	Maximum sound measured 1 m from any position of device [dBA] / [dBC]
Lower level / Higher level -	63,8/93,7dBA	53,5/82,4 Front - dBA
/	/	55,8/85,3 Rear - dBA
/	/	50,9/ 79,6 Right - dBA
/	/	51,9/82,3 Left - dBA
/	/	57,9/87,2 On - dBA
Media results; Lower level / Higher level	/	54,0 dBA/83,36dBA

Supplementary information:

Referenced background sound pressure measurement: _38,2_ dBA

Audio alarm

Operating mode / pulse spacing	Number of pulses			Limit			Pulse spacings			Limit		
	High	Medium	Low	High	Medium	Low	High	Medium	Low	High	Medium	Low
Physiological/technical alarm	10			10								
Between 1 st /2 nd							60,6 ms		50-125 ms			
Between 3 rd /4 th							480 ms		306,7 ms			
Between 5 th / 6 th							1,227 s		0,35-1,3s			
Between 10 th / 1 st							4,987 s		2,5-15s			

Supplementary information:

Referenced background sound pressure measurement: _38,2_ dBA

LUNG VENTILATOR FUNCTIONAL FEATURES

Intended use

FALCO 202 EVO is a lung ventilator for use in emergency rooms, transport, intensive care units and with patients affected by respiratory diseases and it is suitable for ventilation of adult, paediatric and neonatal patients.

Operation principle

- Time cycled at constant volume
- Pressure cycled
- Microprocessor controlled flow
- Spontaneous breath with integrated valve

Pressure automatic compensation (altitude)

Automatic compensation of atmospheric pressure on measured pressure: present (max. 5000 mt)

Automatic leaks compensation	Automatic compensation of mechanical and patient circuit dead space
Leak % visualization	Max 60 l/min (NIV APCV, NIV PSV)
Visualization of the oxygen consumption calculation	Present
Altitude compensation for oxygen sensor	Present
Respiratory parameters default setting	Present (Neonatal, Paediatric, Adult)
Ventilation modalities	- APCV (BILEVEL ST), APCV-TV, PSV (BILEVEL S), PSV-TV (Auto Weaning), VC/VAC, VC/VAC BABY, V-SIMV+PS, P-SIMV+PS, CPAP, APRV - Optional function: HFNC (High Flow Nasal Connection) - SIGH, NEB (Nebulizer), Apnea BACK-UP (PSV, PSV-TV, CPAP), MAN (Manual).
Breathing rate VC/VAC	From 4 to 150 bpm
Inspiratory Time / Expiratory Time (maximum, minimum)	- Ti min = 0.036 sec (minimum inspiratory time) - Ti max = 12 sec (maximum inspiratory time) - Te min = 0.08 sec (minimum expiratory time) - Te max = 13.6 sec (maximum expiratory time)
Breathing rate V-SIMV e P-SIMV	From 1 to 60 bpm
SIMV Inspiratory time	From 0.2 to 5.0 sec.
Tidal volume	- From 100 to 3000 ml (Adult) - From 50 to 400 ml (Paediatric) - From 2 to 100 ml (Neonatal)
I:E ratio	From 1:10 to 4:1
Inspiratory pause	From 0 to 60 % of the inspiratory time
Inspiratory pressure limit	Pinsp: from 2 to 80 cmH ₂ O (in function of low and high-pressure alarm set)
Inspiratory ramp Slope	1, 2, 3, 4 (acceleration slope) - (4 max. acceleration) (in operative modes by pressure only)
PEEP	From OFF, 2 to 50 cmH ₂ O
<i>PEEP adjustment</i>	Microprocessor controlled valve
O₂ concentration	Adjustable from 21 to 100% with electronic integrated mixer.
Trigger detective method	Through sensor (Pressure or Flow)
<i>Pressure trigger (I)</i>	Pressure adjustable from OFF; -1 to -20 cmH ₂ O under PEEP level (step of 1 cmH ₂ O)

<i>Flow trigger (I)</i>	Flow adjustable from OFF; 0.3 to 15 L/min - from 0.3 to 1 L/min (step of 0.1 L/min) - from 1 L/min to 2 L/min (step of 0.5 L/min) - from 2 L/min to 15 L/min (step of 1 L/min)
<i>Trigger E</i>	From 5 to 90 % of the inspiratory peak flow
Inspiratory flow (FLOW)	190 l/min
Flow-by	Automatic
PS (pressure support)	From 2 to 80 cmH ₂ O (PSV, V-SIMV+PS, P-SIMV+PS)
SIGH in VC/VAC modality	- Interval: 40 ÷ 500 bpm (step 1 bpm) - Amplitude: OFF, 10 ÷ 100% of set Tidal Volume (step 10%)
CPAP	Pressure: from 3 to 50 cmH ₂ O
APRV	- Time High and Time Low: from 1 to 200 sec. - Pressure High and Pressure Low: from 3 to 50 cmH₂O.
Functions	- MENU function (SETUP – PATIENT DATA) - Alarms Limits - Graphics visualization (Auto-Range) - INSP Block - EXP Block (max 20 sec.) - O₂ 100% control (O₂ to 100% max. 5 min.) - NEB control (6 l/min) - MAN control (manual ventilation)
NEB	Drug nebulizer: selectable to 6 l/min with automatic compensation on forced ventilation modes and dedicated output
Patient circuit	- Double hose 150 cm. Adult/Paediatric patient circuit (expiratory valve on the ventilator) - Double hose 150 cm. Neonatal patient circuit (expiratory valve on the ventilator)
Software upgrade	USB 1 port
USER INTERFACE	
Touch screen monitor	Module with TFT LED display with touch screen
<i>Dimensions</i>	10,4"
<i>Displaying area</i>	262x163 mm
Display keyboard	Keyboard for rapid access of functions. Encoder knob for: - selection, set up and confirmation of physiological breathing parameters - selection and direct activation of function

Displaying and settings	- Operative Mode setting - Visualization of alarm messages and signals - Setting and monitoring of physiological breathing parameters - Visualization of additional graphs and breathing parameters - MENU function for setting operation parameters - Activation of special functions - Visualization of operative mode, clock, date and time functions - Visualization of software version
Calibration Programs	- Self-Test - Turbine Characterization - Expiratory Flow Sensor Calibration - Usage at High Altitude - VTEc - Nebulizer Enable - ScreenShoot Enable
MENU function - SETUP	- Display (Brightness, Energy Saving, Sound Volume, Touch Audio) - Date & Time - Language - Units (Weight, Height, CO₂, Pressure) - Default (Default parameters: Erase Trend data, Erase Patient data, Setting & Ventilation Default) - Other (NIV Enable, Power Failure, Apnea Time, Change Password, Save to USB) - IRMA/ISA (Gas Sensor) - Supplementary Tests (Expiratory Flow Sensor Calibration, O₂ Sensor Calibration) - Turn Off?
MENU function - PATIENT DATA	The PATIENT DATA can be set or deleted
Alarm Limits	PAW (cmH ₂ O), PEEP (cmH ₂ O), Vte (ml), VM (L/min), O ₂ (%), RR (bpm), EtCO ₂ (%)
Displayed graphics	- CURVES: Pressure (PAW) - Flow - Volume (Vte) - O₂ (CO₂ optional) - LOOPS: Pressure / Volume - Flow / Volume - Pressure/Flow - Graphics: INSP-EXP cycle - Events - Trends
<i>Events</i>	Memory storage up to 2000 machine events including the alarms.
<i>Trends</i>	Storage capacity (72 h) of all measured parameters.
Physiological breathing parameters setting	Vti (ml), RR (bpm), I:E, Pause (%), PEEP (cmH ₂ O), O ₂ (%), Tr. I (L/min - cmH ₂ O), SIGH (Sigh. Amp. (%), Sigh. Int. (b)), Vte (ml), PMax, Pmin, P _{insp} (cmH ₂ O), Slope, BACK-UP parameters, PS (cmH ₂ O), RRsimv (bpm), Ti (s), Ti Max (s), Tr. E (%), CPAP (cmH ₂ O), Pressure High - Low (cmH ₂ O), Time High - Low (s).

<i>Range of measured parameters</i>	- Respiratory rate (range: 0 ÷ 200 bpm) - Rate accuracy ± 1 Bpm - I:E ratio (range 1:99 ÷ 99:1) % of O₂ (range: 0% ÷ 100%) - O₂ accuracy $\pm (2.5\% + 2.5\%$ of the reading) - O₂ from 21% to 90% in less than 80 seconds - Tidal Volume: V_{te}, V_{ti} (range: 0 ÷ 3000 ml) - Expired Minute Volume (range: 0 ÷ 40 l/min) - Expired Volume Accuracy $\pm (15\% + 4\text{ml})$ for volumes > 50ml - Expired Volume Accuracy $\pm (15\%$ or $\pm 15\text{ml})$ whichever is greater for volumes $\leq 50\text{ml}$ - PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH₂O) - Pressure accuracy $\pm (2 \text{ cmH}_2\text{O} + 4\%$ of the reading). - Inspiratory Peak Flow: F_i (range: 1 ÷ 190 l/min) - Expiratory Peak Flow: F_e (range: 1 ÷ 150 l/min) - T_{insp.}, T_{exp}, T_{pause} (range 0.036 ÷ 13.6 sec) - Time accuracy ± 0.2 seconds - Static and Dynamic compliance (range: 1 ÷ 100 ml/cmH₂O) - Resistance (range: 0 ÷ 200 cmH₂O/l/s) - EtCO₂: with optional CO₂ module (range: 0 ÷ 10%) - Leak - % with PEEP 0 or with PEEP 1, - l / min with PEEP ≥ 2 - O₂ consumption (range: 0 ÷ 100l/min)
<i>Displayed parameters</i>	PAW , PEEP, CPAP (cmH ₂ O), RR (bpm), I:E, O ₂ (% - l/min), V _{te} (ml), VM (L/min), EtCO ₂ (%), MAP (cmH ₂ O), P _{plateau} (cmH ₂ O), F _i , F _e (L/min), T _i , T _{pause} , T _e (sec.), R _i (cmH ₂ O/l/s), C _s , C _d (ml/cmH ₂ O), Leak (%)
<i>Additional displayed parameters (optional)</i>	RR SPONT, TV SPONT, MV SPONT, RSBI, TE, WOB, AUTOPEEP
Flow sensor	Magnetic disturbance (patented), multi-usage type
<i>Calibration</i>	Automatic (started by the operator)
<i>Maintenance</i>	By steam disinfection
Oxymeter	Electronic (value displayed in breathing parameters)
<i>Calibration</i>	Automatic (started by the Operator)
CO₂ analyzer	Optional function (Sidestream or Mainstream module available)
ALARMS	
Alarm types	- By MENU: with limits set by the operator - By DEFAULT: the operator cannot set them up
Alarm default setting	Present (Neonatal, Paediatric, Adult)

Alarm priority	High - Mean - Standby
Alarms visualization	Max 3 alarms simultaneously; additional alarms, scroll every 3-5 sec.
Alarms with limits set up by the operator	
Pressure of Airways	High – Low
Respiratory Rate	High – Low
Expiratory Volume	High – Low
Volume Minute	High – Low
PEEP	High – Low
O2 Concentration	High – Low
EtCO2	High – Low (with optional CO2 gas analyser)
On Battery	Alarm occurs in case of failure of external power supply
Apnoea	Low Rate (function of Apnoea BACK-UP)
System alarms	
Low Battery: 50% Remaining	Battery at 50%
Low Battery: 25% Remaining	Battery at 25%
Low Battery	10 Minutes
Battery Disconnected	Yes / No
Battery Overtemperature	Indication of exceeding the temperature limits inside the battery
Circuit Disconnected	Indication of patient circuit disconnected
O2 Supply	Low (< 2,7 bar)
Turbine Failure	Signals in case of a blower fault condition
Turbine Overtemperature	Indication of exceeding the temperature limits inside the turbine
Turbine Overcurrent	Indication of exceeding the current limits inside the turbine
Maintenance	To be carried out when the warning appears
CO2 Analyzer	Sampling Line Clogged, No Sampling Line, Replace Adapter, No Adapter, Unspecified Accuracy, Error, No Breaths, Low/High EtCO2.
SELF-TEST alarms	
Turbine	The correct functioning of the turbine is tested
Oxygen emptying	It is performed a washing of the remaining oxygen present within the lung ventilator, order to measure the offset of the oxygen sensor
INSP.- EXP. Flow sensor	Verification of EXP flow sensor operation
Pressure sensor	Verification of pressure sensor operation through control of PAW reading
Electrovalve	The correct functioning of electro-valve is tested
Patient circuit	Verification of patient circuit
Battery	Checking on battery power
Oxygen sensor	Cell condition

Acoustic alarm	Verification by the user of acoustic signal emission, the confirmation of the test is made by silencing of that alarm
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ACCESSORIES

Supplied Accessories	▪ User's Manual ▪ Double hose patient circuit ▪ Antibacterial filter for patient circuit ▪ Nebulizer set ▪ Power cable ▪ Vehicular cable for 12 Vdc ▪ O2 supply hose ▪ O2 cell
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Optional Accessories	Refer to price list
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SIARE applies the UNI EN ISO 13485:2016 Quality System and the 93/42/EEC.

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