



# C E R T I F I C A T E

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II

Company Name : Mersin AYM Medikal Gıda Ürn. Mob. İnş. San. ve Tic. Ltd. Şti.

Company Address : Hal Mah. Turgut Özal Blv. Mertoç Sit. Dış Kapı No:20 C Blok  
İç Kapı No:67 Akdeniz MERSİN / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II  
(Excluding Section 4)

Product : Central Gas Systems – Class IIa & Class IIb  
- Central Medical Gas Supply Systems (O2, N2O, Vacuum, Air, AGSS) – Class IIb  
- Patient Bedside Unit, Intensive Care Unit, Pendant – Class IIb  
- Terminal Unit (Gas Outlets, Probe) – Class IIb  
- Flowmeter and Oxygen Therapy – Class IIa  
- Pressure Regulator & Turbo – Class IIb & Class IIa  
- Vacuum Regulator – Class IIa  
- Zone Valves – Class IIb  
- Alarm Panels – Class IIb

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UDEM International Certification  
Auditing Training Centre Industry  
and Trade Co. Ltd.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through [www.udemltd.com.tr](http://www.udemltd.com.tr).

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This document containing 3 (three) pages is the Annex of the Certificate with the number M.2016.106.6340 and with the registration date of 08.03.2016 issued for "Mersin AYM Medikal Gıda Ürn. Mob. İnş. San. ve Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. Ltd. Şti. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

Kod	Product Name
A	CENTRAL MEDICAL GAS SUPPLY SYSTEMS - O2-N2O- VACUUM-AIR-AGSS (Class IIb)
A-1	CENTRAL MEDICAL GAS SUPPLY SYSTEMS - O2-N2O
AYM-N <sub>2</sub> -OS-2X1	(N2O) PLANT (2x1 CYLINDER)
AYM-N <sub>2</sub> -OS-2X2	(N2O) PLANT (2x2 CYLINDER)
AYM-N <sub>2</sub> -OS-2X3	(N2O) PLANT (2x3 CYLINDER)
AYM-N <sub>2</sub> -OS-2X4	(N2O) PLANT (2x4 CYLINDER)
AYM-N <sub>2</sub> -OS-2X5	(N2O) PLANT (2x5 CYLINDER)
AYM-N <sub>2</sub> -OS-4X4	(N2O) PLANT (4x4 CYLINDER)
AYM-N <sub>2</sub> -OS-4X5	(N2O) PLANT (4x5 CYLINDER)
AYM-N <sub>2</sub> -OS-5X6	(N2O) PLANT (5X6 CYLINDER)
AYM-N <sub>2</sub> -OS-5X8	(N2O) PLANT (5X8 CYLINDER)
AYM-OS-2X1	OXYGEN PLANT (2x1 CYLINDER)
AYM-OS-2X2	OXYGEN PLANT (2x2 CYLINDER)
AYM-OS-2X3	OXYGEN PLANT (2x3 CYLINDER)
AYM-OS-2X4	OXYGEN PLANT (2x4 CYLINDER)
AYM-OS-2X5	OXYGEN PLANT (2x5 CYLINDER)
AYM-OS-4X4	OXYGEN PLANT (4x4 CYLINDER)
AYM-OS-4X5	OXYGEN PLANT (4x5 CYLINDER)
AYM-OS-5X6	OXYGEN PLANT (5x6 CYLINDER)
AYM-OS-5X8	OXYGEN PLANT (5x8 CYLINDER)
AYM-YBD-N <sub>2</sub> O	N2O Automatic Control and High Pressure Reducing Unit
AYM-YBD-O <sub>2</sub>	O2 Automatic Control and High Pressure Reducing Unit
AYM-LKT-O-ÇP	LIQUID OXYGEN CHANGEOVER UNIT
AYM-KOL1	COLLECTOR - 1 cylinder
AYM-KOL2	COLLECTOR - 2 cylinder
AYM-KOL3	COLLECTOR - 3 cylinder
AYM-KOL4	COLLECTOR - 4 cylinder
AYM-KOL5	COLLECTOR - 5 cylinder
AYM-TIJO	CONNECTION PIPE (Pipe Set - Pig Tail) O <sub>2</sub>
AYM-TIJA	CONNECTION PIPE (Pipe Set - Pig Tail) N <sub>2</sub> O
A-2	CENTRAL MEDICAL GAS SUPPLY SYSTEMS - AIR
AYM-HS-S-2X40	MEDICAL AIR PLANT (2x40 m <sup>3</sup> /h) (500 Lt.)
AYM-HS-S-2X67	MEDICAL AIR PLANT (2x67 m <sup>3</sup> /h) (500 Lt.)
AYM-HS-S-2X100	MEDICAL AIR PLANT (2x100 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-2X130	MEDICAL AIR PLANT (2x130 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-2X165	MEDICAL AIR PLANT (2x165 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-2X220	MEDICAL AIR PLANT (2x220 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-2X270	MEDICAL AIR PLANT (2x270 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-2X330	MEDICAL AIR PLANT (2x330 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-2X400	MEDICAL AIR PLANT (2x400 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-2X510	MEDICAL AIR PLANT (2x510 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-3X40	MEDICAL AIR PLANT (3x40 m <sup>3</sup> /h) (500 Lt.)
AYM-HS-S-3X67	MEDICAL AIR PLANT (3x67 m <sup>3</sup> /h) (500 Lt.)
AYM-HS-S-3X100	MEDICAL AIR PLANT (3x100 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-3X130	MEDICAL AIR PLANT (3x130 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-3X165	MEDICAL AIR PLANT (3x165 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-3X220	MEDICAL AIR PLANT (3x220 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-3X270	MEDICAL AIR PLANT (3x270 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-3X330	MEDICAL AIR PLANT (3x330 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-3X400	MEDICAL AIR PLANT (3x400 m <sup>3</sup> /h) (1000 Lt.)
AYM-HS-S-3X510	MEDICAL AIR PLANT (3x510 m <sup>3</sup> /h) (1000 Lt.)
AYM-K-K-25	CHEMICAL DRYER 25 m <sup>3</sup> /h
AYM-K-K-34	CHEMICAL DRYER 34 m <sup>3</sup> /h
AYM-K-K-45	CHEMICAL DRYER 45 m <sup>3</sup> /h
AYM-K-K-50	CHEMICAL DRYER 50 m <sup>3</sup> /h
AYM-K-K-70	CHEMICAL DRYER 70 m <sup>3</sup> /h
AYM-K-K-85	CHEMICAL DRYER 85 m <sup>3</sup> /h
AYM-K-K-130	CHEMICAL DRYER 130 m <sup>3</sup> /h
AYM-K-K-199	CHEMICAL DRYER 199 m <sup>3</sup> /h
AYM-K-K-300	CHEMICAL DRYER 300 m <sup>3</sup> /h
AYM-K-K-400	CHEMICAL DRYER 400 m <sup>3</sup> /h
A-3	CENTRAL MEDICAL GAS SUPPLY SYSTEMS - VACUUM
AYM-VS-2X40	MEDICAL VACUUM PLANT (2x40 m <sup>3</sup> /h) (500 Lt.)
AYM-VS-2X70	MEDICAL VACUUM PLANT (2x70 m <sup>3</sup> /h) (500 Lt.)
AYM-VS-2X100	MEDICAL VACUUM PLANT (2x100 m <sup>3</sup> /h) (500 Lt.)
AYM-VS-2X150	MEDICAL VACUUM PLANT (2x150 m <sup>3</sup> /h) (1000 Lt.)
AYM-VS-2X220	MEDICAL VACUUM PLANT (2x220 m <sup>3</sup> /h) (1000 Lt.)
AYM-VS-2X305	MEDICAL VACUUM PLANT (2x305 m <sup>3</sup> /h) (1000 Lt.)
AYM-VS-2X400	MEDICAL VACUUM PLANT (2x400 m <sup>3</sup> /h) (1000 Lt.)
AYM-VS-3X40	MEDICAL VACUUM PLANT 3X40 m <sup>3</sup> /h 500 lt tank
AYM-VS-3X70	MEDICAL VACUUM PLANT 3x70 m <sup>3</sup> /h 500 lt tank
AYM-VS-3X100	MEDICAL VACUUM PLANT 3x100 m <sup>3</sup> /h 500 lt tank
AYM-VS-3X150	MEDICAL VACUUM PLANT 3x150 m <sup>3</sup> /h 1000 lt tank
AYM-VS-3X220	MEDICAL VACUUM PLANT 3x220 m <sup>3</sup> /h 1000 lt tank
AYM-VS-3X305	MEDICAL VACUUM PLANT 3x305 m <sup>3</sup> /h 1000 lt tank
AYM-VS-3X400	MEDICAL VACUUM PLANT 3x400 m <sup>3</sup> /h 1000 lt tank



A-4	CENTRAL MEDICAL GAS SUPPLY SYSTEMS - AGSS
AYM-AGS-T-1X30	ANAESTHETIC GAS SCAVENGING PLANT(SINGLE PUMP) 1X30 m3/h
AYM-AGS-T-1X50	ANAESTHETIC GAS SCAVENGING PLANT(SINGLE PUMP) 1X50 m3/h
AYM-AGS-T-1X70	ANAESTHETIC GAS SCAVENGING PLANT(SINGLE PUMP) 1X70 m3/h
AYM-AGS-T-1X100	ANAESTHETIC GAS SCAVENGING PLANT(SINGLE PUMP) 1X100 m3/h
AYM-AGS-T-1X150	ANAESTHETIC GAS SCAVENGING PLANT(SINGLE PUMP) 1X150 m3/h
AYM-AGS-T-1X200	ANAESTHETIC GAS SCAVENGING PLANT(SINGLE PUMP) 1X200 m3/h
AYM-AGS-T-1X250	ANAESTHETIC GAS SCAVENGING PLANT(SINGLE PUMP) 1X250 m3/h
AYM-AGS-T-2X30	ANAESTHETIC GAS SCAVENGING PLANT(DOUBLE PUMP) 2X30 m3/h
AYM-AGS-T-2X50	ANAESTHETIC GAS SCAVENGING PLANT(DOUBLE PUMP) 2X50 m3/h
AYM-AGS-T-2X70	ANAESTHETIC GAS SCAVENGING PLANT(DOUBLE PUMP) 2X70 m3/h
AYM-AGS-T-2X100	ANAESTHETIC GAS SCAVENGING PLANT(DOUBLE PUMP) 2X100 m3/h
AYM-AGS-T-2X150	ANAESTHETIC GAS SCAVENGING PLANT(DOUBLE PUMP) 2X150 m3/h
AYM-AGS-T-2X200	ANAESTHETIC GAS SCAVENGING PLANT(DOUBLE PUMP) 1-2X200 m3/h
AYM-AGS-T-2X250	ANAESTHETIC GAS SCAVENGING PLANT(DOUBLE PUMP) 2X250 m3/h
B	PATIENT BEDSIDE UNIT - INTENSIVE CARE UNIT - PENDANT (Class IIb)
B-1	PATIENT BEDSIDE UNIT
AYM-HB-1	BEDHEAD UNIT - Standard (One Patient)
AYM-HB-2	BEDHEAD UNIT - Standard (Two Patient)
AYM-HB-3	BEDHEAD UNIT - Standard (Three Patient)
AYM-HB-T	BEDHEAD UNIT - TABLEAU TYPE
B-2	INTENSIVE CARE UNIT
AYM-YO-YA-TK	INTENSIVE CARE UNIT - Horizontal - Aluminum Rail - One Patient
AYM-YO-YA-ÇK	INTENSIVE CARE UNIT - Horizontal - Aluminum Rail - Two Patient
AYM-YO-UÇK	INTENSIVE CARE UNIT - Horizontal - Aluminum Rail - Three Patient
AYM-YO-D	INTENSIVE CARE UNIT - Vertical
AYM-YBP-DR-TK	INTENSIVE CARE PENDANT - Vertical - Rigid - One Patient
AYM-YB-TA-T	INTENSIVE CARE PENDANT - CEILING TYPE - SINGLE ARM
AYM-YB-TA-Ç	INTENSIVE CARE PENDANT - CEILING TYPE - DOUBLE ARM
AYM-YB-H	INTENSIVE CARE UNIT - H Type
AYM-YB-ÇK-ÇK	INTENSIVE CARE UNIT, PENDANT TYPE, DOUBLE ARM, DOUBLE HEAD
AYM-YB-KT	INTENSIVE CARE UNIT - INCUBATOR TYPE
AYM-MS	MONITOR STAND
AYM-SA-TR	HOOK
AYM-GMY-6	GAS MODULE - 6 Gas Outlet Provision 140 cm
AYM-GMY-5	GAS MODULE - 5 Gas Outlet Provision 100 cm
AYM-GMY-4	GAS MODULE - 4 Gas Outlet Provision 80 cm
AYM-GMY-3	GAS MODULE - 3 Gas Outlet Provision 60 cm
AYM-GMY-2	GAS MODULE - 2 Gas Outlet Provision 40 cm
AYM-GMY-1	GAS MODULE - 1 Gas Outlet Provision 20 cm
B-3	PENDANT
AYM-DRP-A	ANAESTHETIC PENDANT - vertical, Rigid (floor - false ceiling height max 3,5 mt.)
AYM-DRP-C	SURGICAL PENDANT - vertical, Rigid (floor - false ceiling height max 3,5 mt.)
AYM-PEN-T-A	ANAESTHETIC PENDANT - Single Arm (floor - false ceiling height max 3,5 mt.)
AYM-PEN-T-C	SURGICAL PENDANT - Single Arm (floor - false ceiling height max 3,5 mt.)
AYM-PEN-Ç-A	ANAESTHETIC PENDANT - Double Arm (floor - false ceiling height max 3,5 mt.)
AYM-PEN-Ç-C	SURGICAL PENDANT - Double Arm (floor - false ceiling height max 3,5 mt.)
AYM-PEN-T-A-M	MOTORIZED ANAESTHETIC PENDANT - Single Arm (floor - false ceiling height max 3,5 mt.)
AYM-PEN-G-T-M	MOTORIZED GENERAL PURPOSE PENDANT - Single Arm (floor - false ceiling height max 3,5 mt.)
AYM-PEN-T-C-M	MOTORIZED SURGICAL PENDANT - Single Arm (floor - false ceiling height max 3,5 mt.)
AYM-PEN-Ç-A-M	MOTORIZED ANAESTHETIC PENDANT - Double Arm (floor - false ceiling height max 3,5 mt.)
AYM-PEN-Ç-C-M	MOTORIZED SURGICAL PENDANT - Double Arm (floor - false ceiling height max 3,5 mt.)
C	TERMINAL UNIT (GAS OUTLETS -PROBE) (Class IIb)
AYM-OP-BS	OXYGEN OUTLET - BS
AYM-VP-BS	VACUUM OUTLET - BS
AYM-H4P-BS	AIR (4 BAR) OUTLET - BS
AYM-H7P-BS	AIR (7 BAR) OUTLET - BS
AYM-AP-BS	N2O OUTLET - BS
AYM-OP-DIN	OXYGEN OUTLET - DIN
AYM-VP-DIN	VACUUM OUTLET - DIN
AYM-H4P-DIN	AIR (4 BAR) OUTLET - DIN
AYM-H7P-DIN	AIR (7 BAR) OUTLET - DIN
AYM-AP-DIN	N2O OUTLET - DIN
AYM-OP-NF	OXYGEN OUTLET - NF
AYM-VP-NF	VACUUM OUTLET - NF
AYM-H4P-NF	AIR (4 BAR) OUTLET - NF
AYM-H7P-NF	AIR (7 BAR) OUTLET - NF
AYM-AP-NF	N2O OUTLET - NF
AYM-AG-V	AGSS OUTLET - VENTURY TYPE - WITHOUT PROBE
AYM-AG-P	AGSS OUTLET - PUMP TYPE - WITHOUT PROBE
AYM-PRB-O-BS	OXYGEN PROBE (BS Standart)



AYM-PRB-V-BS	VACUUM PROBE (BS Standart)
AYM-PRB-A-BS	N2O PROBE (BS Standart)
AYM-PRB-H4-BS	AIR (4 BAR) PROBE ( BS STANDARD )
AYM-PRB-H7-BS	AIR (7 BAR) PROBE ( BS STANDARD )
AYM-PRB-O-DIN	OXYGEN PROBE (DIN Standart)
AYM-PRB-V-DIN	VACUUM PROBE (DIN Standart)
AYM-PRB-A-DIN	N2O PROBE (DIN Standart)
AYM-PRB-H4-DIN	AIR (4 BAR) PROBE ( DIN STANDARD )
AYM-PRB-H7-DIN	AIR (7 BAR) PROBE ( DIN STANDARD )
AYM-PRB-O-NF	OXYGEN PROBE (AFNOR Standart)
AYM-PRB-V-NF	VACUUM PROBE (AFNOR Standart)
AYM-PRB-A-NF	N2O PROBE (AFNOR Standart)
AYM-PRB-H4-NF	AIR (4 BAR) PROBE ( NF STANDARD )
AYM-PRB-H7-NF	AIR (7 BAR) PROBE ( NF STANDARD )
AYM-AGTJ-V	AGSS PROBE - DIN - VENTURI TYPE
AYM-AGTJ-P	AGSS PROBE - BS - PUMP TYPE
<b>D</b>	<b>FLOWMETER AND OXYGEN THERAPY (Class Ila)</b>
AYM-NŞ	HUMIDIFYING BOTTLE
AYM-BM	BREATH HOSE
AYM-FLV-BS	FLOWMETER BS
AYM-FLV-DIN	FLOWMETER DIN
AYM-FLV-NF	FLOWMETER NF
AYM-FLV-Ç	FLOWMETER - DOUBLE
AYM-TER-C	THERAPY DEVICE
AYM-FLV-REG	REGULATOR WITH FLOWMETER
AYM-TB-OR	HIGH PRESSURE REGULATOR Connectable to O2 cylinder
AYM-TB-AR	HIGH PRESSURE REGULATOR Connectable to N2O cylinder
<b>E</b>	<b>PRESSURE REGULATOR &amp; TURBO (Class Ila &amp; Class Ila)</b>
AYM-O-R-H	OXYGEN REGULATOR
AYM-O-R-T-B	OXYGEN REGULATOR with outlet connectable to cylinder
AYM-V-R-TRB	TURBO VACUUM REGULATOR
AYM-V-R-TRB-Ş	TURBO VACUUM REGULATOR with Bottle
AYM-H4-VNA	AIR ( 4 BAR) REGULATOR
AYM-H7-VNA	AIR ( 7 BAR) REGULATOR
AYM-N2O-VNA	N2O REGULATOR
AYM-VA-2LT	VACUUM CARRIER -2 Lt.
AYM-VK-2LT	VACUUM JAR 2 LT
AYM-VH	VACUUM HOSE
<b>F</b>	<b>VACUUM REGULATOR (Class Ila)</b>
AYM-V-R-H	VACUUM REGULATOR
<b>G</b>	<b>ZONE VALVES (Class Ila)</b>
AYM-KKA-5	ZONE VALVES 5 GASES
AYM-KKA-4	ZONE VALVES 4 GASES
AYM-KKA-3	ZONE VALVES 3 GASES
AYM-KKA-2	ZONE VALVES 2 GASES
AYM-KKA-1	ZONE VALVES 1 GASES
AYM-VN-8	O2, VACUUM and N2O Valve Ø8 mm (1/4")
AYM-VN-10-12	O2, VACUUM and N2O Valve Ø10- 12mm (3/8")
AYM-VN-15	O2, VACUUM and N2O Valve Ø15 mm (1/2")
AYM-VN-22	O2, VACUUM and N2O Valve Ø22 mm (3/4")
AYM-VN-28	O2, VACUUM and N2O Valve Ø28 mm (1")
AYM-VN-35	O2, VACUUM and N2O Valve Ø35 mm (1 1/4")
AYM-VN-42	O2, VACUUM and N2O Valve Ø42 mm (1 1/2")
AYM-VN-54	O2, VACUUM and N2O Valve Ø54 mm (2")
AYM-VN-76	O2, VACUUM and N2O Valve Ø76 mm (2")
AYM-VN-108	O2, VACUUM and N2O Valve Ø108 mm (2")
<b>H</b>	<b>ALARM PANELS (Class Ila)</b>
AYM-AP-5	ALARM PANELS 5 GASES
AYM-AP-4	ALARM PANELS 4 GASES
AYM-AP-3	ALARM PANELS 3 GASES
AYM-AP-2	ALARM PANELS 2 GASES
AYM-AP-1	ALARM PANELS 1 GASES