



EC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Üzümcü Tıbbi Cihaz Ve Medikal Gaz Sistemleri San. ve Tic. A.Ş.

Company Address : Oğulbey Mah. Kumludere Cad. No:1/1A Gölbaşı ANKARA / TURKEY

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

Product : Medical Gas System and Electrosurgical Products - Class IIb, IIa

GMDN : 10217, 42549, 36271, 35630, 36810, 37512, 34849, 47860, 47860, 43438, 44809, 15615, 36778, 35030, 11067

Product Types are attached.

Certificate Number : M.2019.106.12408
Report Number : MD.3754.IB
Initial Assessment Date : 28.05.2019
Registration Date : 09.08.2019
Revision Date /No : 26.08.2020/02
Expiry Date : 27.05.2024



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

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive 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. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. 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



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemitd.com.tr www.udem.com.tr

Medical Gas Systems					
Flowmeter - Class IIb GMDN: 42549					
Models					
1200.05	1200.10	1200.15	1200.25	1200.30	1200.00B
1200.00N	1200.00E	1200.05U	1200.10U	1200.15U	1274.00
1200.20U	1220.05	1220.10	1220.15	1220.20	1222.05
1230.05	1230.10	1230.15	1270.00	1273.00	
Bed Head Units and Pendants					
Bed Head Units – Class IIb GMDN: 36271					
1000.10	1000.60	1030.10	1035.20	1035.75	1040.30
1000.20	1000.70	1030.20	1035.30	1040.09	1045.10
1000.30	1000.85	1030.30	1035.55	1040.10	1045.20
1000.50	1000.95	1035.10	1035.65	1040.20	1065.10
1065.11	1065.13	1065.15	1065.30	1070.30	
1065.12	1065.14	1065.20	1068.10	1070.50	
Bed Head Units and Pendants					
Pendants - Sınıf IIb GMDN: 35630,36810					
5070.30	5070.50	5070.65	5070.75L	5070.81	1085.80
5070.40	5070.60	5070.75	5070.80	5075.45	1085.90
5070.45	5070.61	5070.76	5070.80L	5075.50	
Medical Gas Terminal Units / Medical Gas Outlets and Probes / Medical Gas Outlets - Class IIb GMDN: 36271					
Models					
1001.05	1001.59	1003.59	1004.58	1005.52	1001.05
1001.50	1003.50	1004.05	1004.59	1005.58	1001.50
1001.51	1003.51	1004.50	1005.05	1005.59	1001.51
1001.52	1003.52	1004.51	1005.50	1008.51	1001.52
1001.58	1003.58	1004.52	1005.51		1001.58
Medical Gas Terminal Units / Medical Gas Outlets and Probes / Vacuum Outlets - Class IIb GMDN: 37512					
Models					
1002.05	1002.51	1002.58	1002.50	1002.52	1002.59
Medical Gas Terminal Units / Medical Gas Outlets and Probes / AGSS - Anaesthetic Gas Scavenging Outlets and Probes					
- Class IIb GMDN: 34849					
Models					
1007.05	1007.10	1017.10	1607.05	1607.10	2027.10
Medical Gas Terminal Units / Medical Gas Outlets and Probes / Probes for Compressed Medical Gases					
- Class IIb GMDN: 36271					
Models					
1601.05	1603.10	1604.15	1241.05	1243.10	1245.15
1601.10	1603.15	1605.05	1241.10	1243.15	1246.05
1601.15	1604.05	1605.10	1241.15	1245.05	1246.10
1603.05	1604.10	1605.15	1243.05	1245.10	1246.15
Medical Gas Terminal Units / Medical Gas Outlets and Probes / Probes for Vacuum					
- Class IIb GMDN: 37512					
Models					
1602.05	1602.15	1242.10	1244.05	1244.15	
1602.10	1242.05	1242.15	1244.10		

Regulators for Use with Medical Gases / Pressure Regulators for Terminal Units (OTC included) - Class IIb GMDN: 47860					
Models					
1401.05	1403.05	1404.05	1405.05	OTC-50	
1401.10	1403.10	1404.10	1405.10	OTC-51	
1401.15	1403.15	1404.15	1405.15	OTC-52	
1401.05	1403.05	1404.05	1405.05	OTC-50	
Regulators for Use with Medical Gases / High Pressure Reducers - Class IIb GMDN: 47860					
Models					
4000.10	4000.15	4000.30	4000.80		
4000.10A	4000.15A	4000.30A	4000.80A		
Regulators for Use with Medical Gases / Regulators for Use with Cylinders - Class IIb GMDN: 43438					
Models					
OBR-50	OBR-51	OBR-80			
Regulators for Use with Medical Gases / Regulators for Use with Terminal Units - Class IIb GMDN: 44809					
Models					
1402.05	1402.10R	1422.10	1520.00D		
1402.10	1402.15R	1422.15	1420.20D		
1402.15	1420.20N	1422.20	1420.20B		
1402.05R	1422.05	1520.00B	1520.00N		
Pipelines and Stations for Medical Gases / Area Gas Control Boxes- Class IIb GMDN: 36271					
Models					
956280601	956280603	956280901	956280903	956281201	956281203
956281501	956281503	956280302	956280304	956280602	956280604
956280902	956280904	956281202	956281204	956281502	956281504
956280301	956280303				
Pipelines and Stations for Medical Gases / Oxygen Station- Class IIb GMDN: 36271					
Models					
MOS-4M	MOS-10	MOS-16	MOS-30	MTO-2	
MOS-6	MOS-11	MOS-20	MOS-40		
Pipelines and Stations for Medical Gases / Nitrous Oxide Station- Class IIb GMDN: 36271					
Models					
MAS-4M	MAS-10	MAS-16	MAS-30	MTA-2	
MAS-6	MAS-11	MAS-20	MAS-40		
Pipelines and Stations for Vacuum / Vacuum Station (Vertical)- Class IIb GMDN: 15615					
Models					
VRD-42		VRD-102	VRD-202		
VRT-43		VRT-103	VRT-203		
Pipelines and Stations for Vacuum / Vacuum Station (Horizontal)- Class IIb GMDN: 15615					
Models					
VYD-42		VYD-102	VYD-202		
VYT-43		VYT-103	VYT-203		
Pipelines and Stations for Vacuum / Vacuum Station (Mini)- Class IIb GMDN: 15615					
Models					
VPY-70					
Central Vacuum Trolley- Class IIa GMDN: 36778					
Models					

This document containing 3 (three) pages is the Annex of the Certificate with the revision number 02, with the number M.2019.106.12408 and with the registration date of 09.08.2019 and with the revision date of 26.08.2020 issued for "Üzümçü Tıbbi Cihaz Ve Medikal Gaz Sistemleri San. ve Tic. A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

30400	30402	30403	30405
Electrosurgical Units			
Electrosurgical Cautery- Class IIb GMDN: 35030			
Models			
EK-160	EK-250	EK-410	
Cryotherapy Device - Class IIa GMDN: 11067			
Models			
KRY-10	KRY-10S		
Surgical Suctions Mobile Series – Class IIa GMDN: 10217			
Models			
Amb	PA-1R	PA-2	PA-2S
Surgical Suctions Novela Series – Class IIa GMDN: 10217			
Models			
Novela	Novela Extractor	Vela	



SERTİFİKA CERTIFICATE

TS EN ISO 13485:2016 Tıbbi Cihazlar Kalite Yönetim Sistemi
Medical Devices Quality Management System as per TS EN ISO 13485:2016

In accordance with BBS procedures, it is hereby certified that



ÜZÜMCÜ TIBBİ CİHAZ VE MEDİKAL GAZ SİSTEMLERİ SAN. VE TİC. A.Ş.

Oğulbey Mahallesi 3058 Cadde No:2 Gölbaşı / ANKARA / 06830

BBS prosedürlerine göre yukarıda belirtilen standart şartlarını karşıladığını kanıtlamıştır.

Applies a management system in line with the above standard for the following scope

Kapsam

Scope

Ameliyathane ekipmanları, yoğun bakım ve acil servis ekipmanları, hasta odası ve klinik ekipmanları, sterilizasyon ve paslanmaz çelik ekipmanları, medikal gaz sistemi ve ekipmanları, hastane, ambulans ve laboratuvarların ekipmanlarının tasarımı, geliştirilmesi, üretimi, montajı, dağıtımı ve servisi.

Operating room equipment, intensive care and emergency service equipment, patient room and clinical equipment, sterilization and stainless-steel equipment, medical gas system and equipment, hospital, design of ambulance and laboratories equipment, development, manufacture, assembly, distribution and service of equipment.

Sertifika No / Certificate No 1256-01

İlk Belge Tarihi / Initial Certification 28.04.2022

Belge Geçerlilik Tarihi / Valid Until 27.04.2025


Belgelendirme Kuruluşu / Certification Body
BBS A.Ş.

Ankara, 28.04.2022

Belgelendirme BBS tetkik ve belgelendirme prosedürlerine uygun olarak gerçekleşmiştir ve düzenli gözetim tetkiklerine tabidir.
Certification was conducted in accordance with BBS auditing and certification procedures and is subject to regular surveillance audits.



TÜRKAK BDS NO
YS-2505-590C

Bu sertifikanın geçerlilik durumu www.bbsas.com.tr ve tbds.turkak.org.tr adreslerinden doğrulanabilir.

Belge üzerindeki karekod QR okuyucu ile okutulmak suretiyle de doğrulama yapılabilir.

The authenticity of this certificate may be verified at www.bbsas.com.tr and tbds.turkak.org.tr.

The authenticity may also be checked with the QR Code above.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.

Cevizlidere Mah. 1246 Sokak No: 4/20 P.K. 06520 ÇANKAYA / ANKARA / TÜRKİYE

www.bbsas.com.tr

OPERATING TABLE

Model: OM-6N

Order Number: 11.1109



Product Features

General Features:

The Number of Mattresses	: 6
Mattress Materials	: PU
Mattress Thickness	: 50mm
Maximum carrying capacity	: 250 kg(all positions) 350 kg(zero position)
Table Top Dimension	: 600x2200mm (±30mm)
Wheel Features	: One Swivel Front Wheel,(Ø80x30mm) Two Dual Rear Wheels(Ø125x32mm)
Classification	: Class I (MDD 93/42 EEC)
Standards	: EN 60601-1, EN 60601-2-46
Product Documentation	: CE ve TSE

Electrical Properties:

Inlet Voltage	: 220-240 VAC / 50-60 Hz
Working Voltage	: 24 VDC
Fuse Type:	: 2 x 1,25A glass fuse
Battery Duration	: 30 Full Movement
Battery Charge Time	: 9 Hour
Electrical Protection Class	: Class I

Packaging Features:

Dead Weight	: 216 kg
Gross Weight	: 261 kg
Packaging Dimensions	: 780x1700x1000mm

Material Specifications:

X-Ray Permeability Compact and PU Materials are Used For Table Top
Main Body is Made Of Stainless Steel(AISI 316L, DIN X2CrNiMo17-12-2)
Table Top Mattress has Nano surface protection.
Pins and adapters on the table body is made of copper-coated.

Table Positions:

OM-6N Operating Tables,Electrical Movements are Operated by Electrical Motors
and Mechanical Movements are Operated by Gas Springs
Kidney Surgery Position is Operated by Mechanical lever

Electrical Movements:

Height Adjustment
Back Rest
Trendelenburg/Reverse Trendelenburg
Lateral Tilt Movement
Sliding

Mechanical Movements:

Head Rest Movement
Back Rest, Kidney Surgery Position (250° or 130 mm)

Leg Rests,Up/Down

Leg Rests,Right/Left

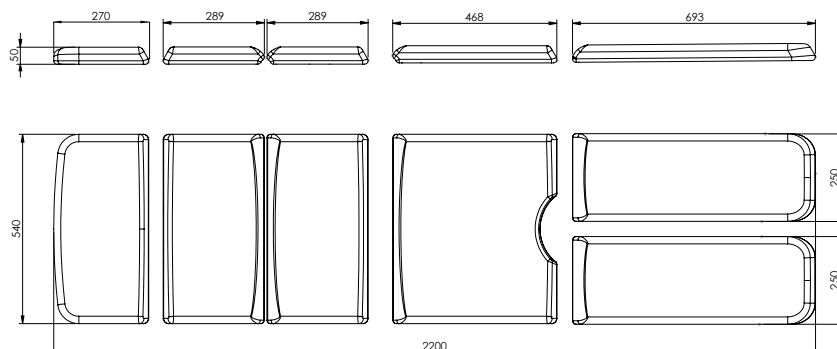
Accessories:

OM-100	: Anaesthesia Screen
OM-110	: Infusion Rod
OM-120	: Arm Support,Pair
OM-150	: Body Strap
OM-220	:Knee Support

Mattress Properties

Antibacterial Feature and Cleanable
Detachable PU Mattresses

Mattress Dimensions



OPERATING TABLE

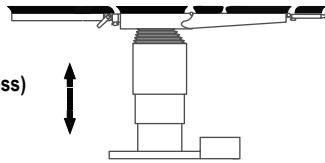
Model: OM-6N

Table Positions :

Height Adjustment :

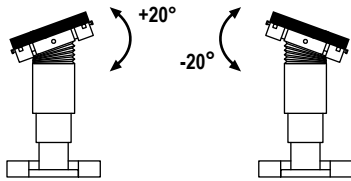
2x6000 N Electromechanic motors for up / down movement

800 mm - 1200 mm (with mattress)



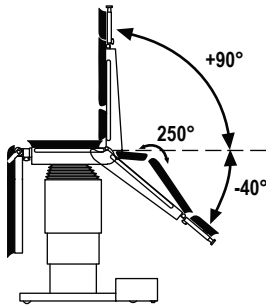
Lateral Tilt Movement :

1x6000 N electromechanic motors for lateral tilt movement



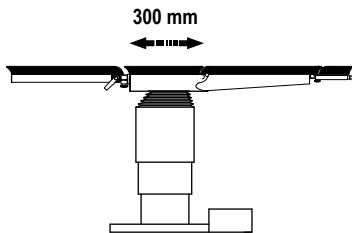
Back Rest Movement :

1x6000 N electromechanic motors and 1x600 N gas springs



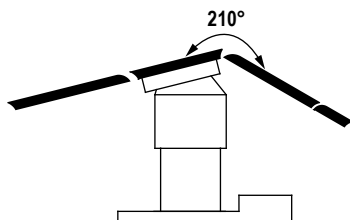
Sliding Movement :

1x6000 N Electromechanic motors for sliding movement



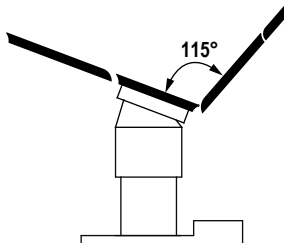
Flex:

Electromechanic engine uses for flex movement



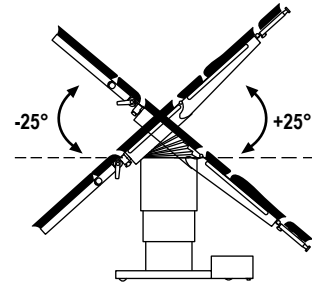
Reflex:

Electromechanic engine uses for Reflex movement



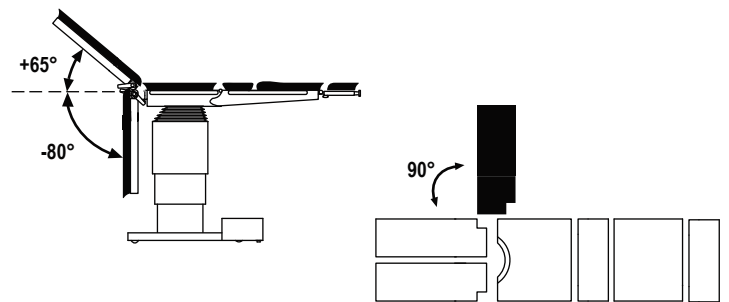
Trendelenburg -Reverse Trendelenburg

1x6000 N electromechanic motors and 1x600 N gas springs



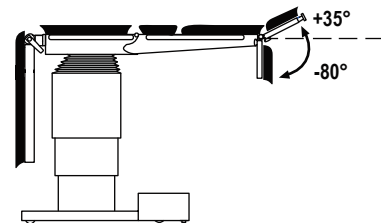
Leg Rests, Up/Down :

2x500 N gas springs



Head Rest Movement :

2x300 N gas springs for head rest movement



Positions:

Height Adjustment,
Back Rest Movement
Trendelenburg - Reverse Trendelenburg,
Lateral Tilt Movement,
Sliding Movement

Memory Capacity:

5 different position to record feature
10 different function buttons manages
the basic movements
There is 3 remote control in completion.

