

MEDICAL DEVICES CHANGE CONFIRMATION FORM

The validity of the Change Confirmation Form expires when the validity period of related EC Certificate/s expires. The Change Confirmation Form alone has no function.

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

Company Address : Oğulbey Mahallesi 3058. Cad. No:2 Gölbaşı ANKARA / TURKEY

Related Directive : 93/42/EEC Medical Devices Directive

Definition of Change : Surgical Aspirator Device Portable Series, 10217 GMDN number has been changed to 47367.
Surgical Aspirator Device Novela Series, 10217 GMDN number has been changed to 63642.

Number of Related Certificate : M.2019.106.12408

Report Number : MD.3754

Issue Date : 05.10.2021

Revision Date : 04.07.2022

Revision Number : 01



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

UDEM declares that the mentioned changes have been confirmed as non-significant changes according to MDR Article 120(3) and MDCG 2020-3 with this Change Confirmation Form. This form has been prepared to be shared with authorities or third parties upon request.



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
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REVISION REVIEW APPROVAL FORM

When the validity period of the EC/ Design (if exists) Certificate to which it is attached expires, the validity period of the Revision Review Approval Form will also expire. Revision Review Approval Form has no function if used alone.

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

Company Address : Oğulbey Mahallesi 3058. Cad. No:2 Gölbaşı ANKARA / TURKEY

Related Directive : 93/42/EEC Medical Devices Directive

Definition of Change : Company Adress Change.

Certificate Number Which It is Attached : M.2019.106.12408

Report Number : MD.3754

Issue Date : 05.10.2021

Revision Date : -

Revision Number : 00



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

Revision Review Approval Form has been prepared for the products mentioned above. UDEM declares that the listed products are non-significant changes according to MDR Article 120-3 and MDCG 2020-3. This form has been prepared to be shared with authorized authorities and 3rd parties upon request.



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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



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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



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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.

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		





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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					





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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

