



C E R T I F I C A T E

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

Company Name : Teknomek Medikal Malzemeleri Sanayi ve Ticaret Ltd. Şti.

Company Address : Halicioğlu Mah. Okumuşoğlu Sokak No:2 K:5 D:5 Beyoğlu
ISTANBUL / TURKEY

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

Product : Sterile Silicone oil - Class IIb
Sterile Ophthalmic Gases - Class IIb
Sterile Viscoelastik Holution, Sodium Hyaluronate - Class IIb

GMDN : 35907, 45125

Product Types are attached.

Certificate Number : M.2017.106.9081

Report Number : MD.3437.YB

Initial Assessment Date : 30.05.2017

Registration Date : 18.12.2017

Recertification Assessment Date : 20.12.2019

Reissue Date / No : 06.04.2020/01

Revision Date /No : -

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 company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.



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This document containing 1 (one) pages is the Annex of the Certificate with the number M.2017.106.9081 and with the registration date of 18.12.2017 and with the re-issue date 06.04.2020 issued for "Teknomek Medikal Malzemeleri Sanayi ve Ticaret Ltd. Şti." 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.

Sterile Silicone Oil - Class IIb						
EAN Code Number	Code		Product Name	Sterilization Method	GMDN	
8680548905429	VT	V1	Silicone Oil 1000 cSt Vial	Steam Sterilization	45125	
8680548905436	VT	S1	Silicone Oil 1000 cSt Syringe	Steam Sterilization	45125	
8680548905443	VT	V13	Silicone Oil 1300 cSt Vial	Steam Sterilization	45125	
8680548905450	VT	S13	Silicone Oil 1300 cSt Syringe	Steam Sterilization	45125	
8680548905504	VT	V50	Silicone Oil 5000 cSt Vial	Steam Sterilization	45125	
8680548905511	VT	S50	Silicone Oil 5000 cSt Syringe	Steam Sterilization	45125	
Sterile Ophthalmic Gases - Class IIb						
EAN Code Number	Code		Product Name	Sterilization Method	GMDN	
8680548905122	VT	10SFA	Sulfur Hexafluoride Aeresol SF6 10ml	EO Sterilization	45125	
8680548905139	VT	30SFA	Sulfur Hexafluoride Aeresol SF6 30ml	EO Sterilization	45125	
8680548905146	VT	50SFA	Sulfur Hexafluoride Aeresol SF6 50ml	EO Sterilization	45125	
8680548905207	VT	10CFA	Octafluoropropane Aeresol C3F8 10ml	EO Sterilization	45125	
8680548905214	VT	30CFA	Octafluoropropane Aeresol C3F8 30ml	EO Sterilization	45125	
8680548905221	VT	50CFA	Octafluoropropane Aeresol C3F8 50ml	EO Sterilization	45125	
Sterile Viscoelastic Solution - Class IIb						
EAN Code Number	Code		Product Name	Specification	Sterilization Method	GMDN
8680548905641	CT	1V55M	Sodium Hyaluronate	0.55ml 1%	Steam Sterilization	35907
8680548905658	CT	1V85M	Sodium Hyaluronate	0.85ml 1%	Steam Sterilization	35907
8680548905665	CT	1V1M	Sodium Hyaluronate	1ml 1%	Steam Sterilization	35907
8680548916371	CT	1V15M	Sodium Hyaluronate	1.5ml 1%	Steam Sterilization	35907
8680548905672	CT	1V2M	Sodium Hyaluronate	2ml 1%	Steam Sterilization	35907
8680548905689	CT	12V55M	Sodium Hyaluronate	0.55ml 1,2%	Steam Sterilization	35907
8680548905696	CT	12V85M	Sodium Hyaluronate	0,85ml 1,2%	Steam Sterilization	35907
8680548905702	CT	12V1M	Sodium Hyaluronate	1ml 1,2%	Steam Sterilization	35907
8680548916388	CT	12V15M	Sodium Hyaluronate	1.5ml 1,2%	Steam Sterilization	35907
8680548905719	CT	12V2M	Sodium Hyaluronate	2ml 1,2%	Steam Sterilization	35907
8680548905726	CT	14V55M	Sodium Hyaluronate	0.55ml 1,4%	Steam Sterilization	35907
8680548905733	CT	14V85M	Sodium Hyaluronate	0.85ml 1,4%	Steam Sterilization	35907
8680548905740	CT	14V1M	Sodium Hyaluronate	1ml 1,4%	Steam Sterilization	35907
8680548916395	CT	14V15M	Sodium Hyaluronate	1.5ml 1,4%	Steam Sterilization	35907
8680548905757	CT	14V2M	Sodium Hyaluronate	2ml 1,4%	Steam Sterilization	35907
8680548905764	CT	16V55M	Sodium Hyaluronate	0.55ml 1,6%	Steam Sterilization	35907
8680548905771	CT	16V85M	Sodium Hyaluronate	0.85ml 1,6%	Steam Sterilization	35907
8680548905788	CT	16V1M	Sodium Hyaluronate	1ml 1,6%	Steam Sterilization	35907
8680548916401	CT	16V15M	Sodium Hyaluronate	1.5ml 1,6%	Steam Sterilization	35907
8680548905795	CT	16V2M	Sodium Hyaluronate	2ml 1,6%	Steam Sterilization	35907
8680548905801	CT	18V55M	Sodium Hyaluronate	0.55ml 1,8%	Steam Sterilization	35907
8680548905818	CT	18V85M	Sodium Hyaluronate	0.85ml 1,8%	Steam Sterilization	35907
8680548905825	CT	18V1M	Sodium Hyaluronate	1ml 1,8%	Steam Sterilization	35907
8680548916418	CT	18V15M	Sodium Hyaluronate	1.5ml 1,8%	Steam Sterilization	35907
8680548905832	CT	18V2M	Sodium Hyaluronate	2ml 1,8%	Steam Sterilization	35907
8680548905849	CT	2V55M	Sodium Hyaluronate	0.55ml 2%	Steam Sterilization	35907
8680548905856	CT	2V85M	Sodium Hyaluronate	0.85ml 2%	Steam Sterilization	35907
8680548905863	CT	2V1M	Sodium Hyaluronate	1ml 2%	Steam Sterilization	35907
8680548916425	CT	2V15M	Sodium Hyaluronate	1.5ml 2%	Steam Sterilization	35907
8680548905870	CT	2V2M	Sodium Hyaluronate	2ml 2%	Steam Sterilization	35907
8680548905887	CT	24V55M	Sodium Hyaluronate	0.55ml 2,4%	Steam Sterilization	35907
8680548905894	CT	24V85M	Sodium Hyaluronate	0.85ml 2,4%	Steam Sterilization	35907
8680548905900	CT	24V1M	Sodium Hyaluronate	1ml 2,4%	Steam Sterilization	35907
8680548916432	CT	24V15M	Sodium Hyaluronate	1.5ml 2,4%	Steam Sterilization	35907
8680548905917	CT	24V2M	Sodium Hyaluronate	2ml 2,4%	Steam Sterilization	35907
8680548905924	CT	3V55M	Sodium Hyaluronate	0.55ml 3%	Steam Sterilization	35907
8680548905931	CT	3V85M	Sodium Hyaluronate	0.85 ml 3%	Steam Sterilization	35907
8680548905948	CT	3V1M	Sodium Hyaluronate	1ml 3%	Steam Sterilization	35907
8680548916449	CT	3V15M	Sodium Hyaluronate	1.5ml 3%	Steam Sterilization	35907
8680548905955	CT	3V2M	Sodium Hyaluronate	2ml 3%	Steam Sterilization	35907