

EU Quality Assurance Certificate

Medical Devices Regulation (EU) 2017/745 Annex XI Part A
(Class Is, Im and Ir Devices)



Certificate Number: M.2023.MDR.1021

Manufacturer Name : Dilamed Tıbbi Ürünler Sanayi ve Ticaret A.Ş.
Manufacturer Address : Yazıbaşı Mahallesi Fatma Tonkuş Cad. N:24, Torbalı,
İzmir, Türkiye
Single registration number-SRN : TR-MF-000025304
Authorised Representative Name : NA
(If applicable)
Authorised Representative Address : NA
Product Scope : See the product list on the following page(s).

Based on the conformity assessment for the abovementioned manufacturer's quality assurance system in accordance with (EU) 2017/745 Medical Devices Regulation Annex XI Part A, UDEM Adriatic d.o.o hereby declares that the requirements of Annex XI Part A of the Regulation (EU) 2017/745 have been met for the listed products in this certificate.

The manufacturer has established, documented and implemented a quality management system, which is subject to periodic surveillance assessments by UDEM Adriatic d.o.o. according Annex XI Part A Section 7 of the aforementioned Regulation.

For the devices covered by this certificate, the involvement of UDEM Adriatic d.o.o. in the conformity assessment procedures is limited: in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions; in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The report referenced below summarizes the result of assessments/examinations and includes reference to relevant CS, harmonized standards and test reports.

Report Number : MDR.1570
Date of Issue : 03/08/2023
Recertification Date : -
Reissue Date/No : 05/01/2024/01
Date of Expiry : 02/08/2028

UDEM Adriatic d.o.o.
General Manager



If any, Previous Certificate(s) No: -

UDEM Adriatic d.o.o. is a Notified Body (identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

Address: Radnička cesta 54/ R3 Zagreb - Croatia
E-Mail: info@udemadriatic.com **Web:** www.udemadriatic.com

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PRODUCT LIST COVERED BY THE CERTIFICATE

PRODUCT NAME	RISK CLASS	EMDN CODE	MODEL/TYPE
STERILE DRAPES	Class Is	Z1399	Fluoroscopy Drape
			Microscope Drape
			Mini C-Arm Drape
			Scopy Drape
STERILE EQUIPMENT AND CAMERA COVERS	Class Is	Z1399	3-piece C-Arm Set (Springbow)
			C-Arm Cover Set with Clips + Foot Switch Cover
			Accordion Drill Cover
			Camera Cover
			Cardboard Camera Cover
			Cardboard Camera Cover with Elastic Tip
			Cardboard Camera Cover with White Elastic Tip
			C-Arm Arc Cover with Clips
			C-Arm Cover with Clips
			C-Arm Cover, U-Shaped, Full Coverage
			C-Arm Uni-protection Cover
			Circled Ring Camera Cover
			Concertina/Accordion Folded Camera Cover
			Decontamination Tank Cover
			Drill Cover with Cardboard Insert
			Drill Cover, Open Ended
			Endoscopy Mouthpiece
			Exoscope Cover
			Foot Switch Cover
			Microscope Drape Handle Protectors
			Microscope Drape Handle Protectors Set
			O-Arm Cover
			Operating Room Ceiling Lamp Hand Handle Cover (Light Handle Cover)
			PE Probe Cover
			PE Probe Cover Set
			Probe Cover
			PU Probe Cover

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			PU Probe Cover Set
			Skin Marking Set
			Telescopic Camera Cover
			Telescopic Camera Cover with Elastic Tip
			Telescopic Camera Cover with White Elastic Tip
			Ultrasound Probe Cover
			Universal Sponge Light Handle Cover

Conditions for or limitations to the validity of this certificate : none

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CERTIFICATE HISTORY		
Rev. No.	Rev. Date	Description of Revision
00	19/12/2022	Initial Certification
01	05/01/2024	New models were added



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CERTIFICATE



Bu Sertifika / This Certificate

DİLAMED TIBBİ ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

Firmasının / Of the Company

**Yazıbaşı Mah. Fatma Tonkuş Cad. No:24 İç Kapı No:1
Torbalı / İzmir / Türkiye**

QRS Belgelendirme tarafından denetlenmiş ve uygulamakta olduğu
Tıbbi Cihaz Yönetim Sisteminin

Is audited by QRS Certification and applied

Medical Devices Management System meet the requirements of

ISO 13485:2016

Şartlarının aşağıdaki kapsamda uygulanmakta olduğu gözlenmiştir.

It has been observed that the conditions are applied within the following scope

Belgelendirme Kapsamı / Certification Scope

HASTANE, KLİNİK, POLİKLİNİK, LABORATUAR VE DOKTOR MUAYENEHANELERİ İLE SAĞLIK KURULUŞLARININ İHTİYAÇLARI OLAN TIBBİ CİHAZ VE YEDEK PARÇALARI (KILIF GRUBU, ENDOSKOPI AĞIZLIĞI, CİLT İŞARETLEME SETİ, UZATMA HATTI, MUKUS TOPLAMA KABI, SMEAR FIRÇASI, SMEAR KABI, GÖBEK KLEMPİ, POUCH AÇACAĞI, SABİTLEYİCİ GRUBU, FOTOTERAPİ GÖZ BANDI GRUBU, SAÇ YIKAMA BONESİ, VÜCUT TEMİZLEME LİFİ, DEZENFEKTAN, KUSMUK TORBASİ, BÖBREK KÜVETİ, İDRAR TORBASİ, %7,5 POVIDONE İYOT EMDİRİLMİŞ CERRAHİ TIRNAK FIRÇASI, %4 KLOREHEKSİDİN GLUKONAT EMDİRİLMİŞ CERRAHİ TIRNAK FIRÇASI, KURU CERRAHİ TIRNAK FIRÇASI) ÜRETİM VE SATIŞ HİZMETLERİ

MEDICAL DEVICES AND SPARE PARTS FOR HOSPITALS, CLINICS, POLYCLINICS, LABORATORIES AND DOCTOR'S OFFICES AND HEALTH INSTITUTIONS (DRAPE GROUP, ENDOSCOPY MOUTHPIECE, SKIN MARKING SET, EXTENSION LINE, MUCUS COLLECTOR, URIMETER, SMEAR BRUSH, SMEAR CONTAINER, UMBILICAL CORD CLAMP, POUCH PERFORATOR, STABILIZER GROUP, PHOTOTHERAPY EYE BAND GROUP, HAIR WASHING CAP, BODY CLEANING FIBER, DISINFECTANT, EMESIS BAG, KIDNEY DISH, BEDPAN COVER, VALVE URINE BAG, 7% POVIDINE IODINE IMPREGNATED SURGICAL HAND BRUSH, 4% CHLORHEXIDINE GLUCONATE IMPREGNATED SURGICAL HAND BRUSH, DRY SURGICAL HAND BRUSH) PRODUCTION AND SALES SERVICES

Sertifika Numarası : MDMS-22-2807-DİL

Certificate Number

Sertifika İlk Basım Tarihi : 28.07.2022

Certificate Date of First Printing

Sertifika Son Basım : 26.07.2023

Certificate Last Edition

Sertifika Geçerlilik Tarihi : 27.07.2024

Certificate Validity Date

Sertifika Revizyon No ve Tarih : 00

Certificate Revision Number and Date

Sertifika Periyot Tarihi : 28.07.2022 / 27.07.2025

Certificate Period Date



[Signature]

Onay / Approval





DİLAMED
Tıbbi Ürünler A.Ş.

Technical Data Sheet

MICROSCOPE DRAPE



Sterile Microscope Drape

It is a sterile, temporary-use, non-invasive, disposable medical device consisting of polyethylene transparent film and components, which wraps the microscope and serves as a physical barrier to prevent mutual contamination between the microscope and the patient/healthcare personnel during the surgical procedure.

Available Models & Sizes

Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 117x163 cm	DLM0001-75
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 117x203 cm	DLM0001-76
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 117x225 cm	DLM0001-77
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 117x267 cm	DLM0001-78
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 117x305 cm	DLM0001-79
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 117x381 cm	DLM0001-80
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 120x225 cm	DLM0001-81
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 120x250 cm	DLM0001-82
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 120x260 cm	DLM0001-83
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 120x300 cm	DLM0001-84
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 120x400 cm	DLM0001-85
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 122x210 cm	DLM0001-86
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 122x260 cm	DLM0001-87
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 122x270 cm	DLM0001-88
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 132x267 cm	DLM0001-89
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 132x305 cm	DLM0001-90
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 132x381 cm	DLM0001-91
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 132x391 cm	DLM0001-92

Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 137x267 cm	DLM0001-93
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 137x305 cm	DLM0001-94
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 137x381 cm	DLM0001-95
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 137x391 cm	DLM0001-96
Microscope Drape 65 mm Elastomer Sloped Lens Housing WxL 132x342 cm	DLM0001-97
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 117x203 cm	DLM0001-136
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 117x225 cm	DLM0001-137
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 117x267 cm	DLM0001-138
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 117x305 cm	DLM0001-139
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 117x381 cm	DLM0001-140
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 120x225 cm	DLM0001-141
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 120x250 cm	DLM0001-142
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 120x260 cm	DLM0001-143
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 120x300 cm	DLM0001-144
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 120x400 cm	DLM0001-145
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 122x210 cm	DLM0001-146
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 122x225 cm	DLM0001-147
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 122x250 cm	DLM0001-148
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 122x260 cm	DLM0001-149
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 122x270 cm	DLM0001-150
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 122x300 cm	DLM0001-151

Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 132x225 cm	DLM0001-152
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 132x267 cm	DLM0001-153
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 132x300 cm	DLM0001-154
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 132x305 cm	DLM0001-155
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 132x381 cm	DLM0001-156
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 132x391 cm	DLM0001-157
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 132x400 cm	DLM0001-158
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 137x225 cm	DLM0001-159
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 137x267 cm	DLM0001-160
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 137x300 cm	DLM0001-161
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 137x305 cm	DLM0001-162
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 137x381 cm	DLM0001-163
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 137x391 cm	DLM0001-164
Microscope Drape 68 mm Elastomer Sloped Lens Housing WxL 137x400 cm	DLM0001-165

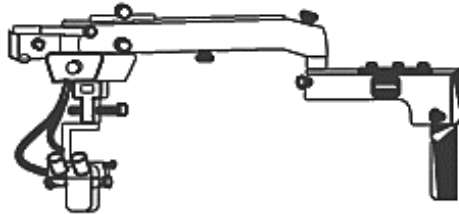
Features

- Specially folded for easy application.
- High quality lens system for especially clear viewing.
- Adhesive tape and straps ensure the cover stays securely in place.
- Compatible with Carl Zeiss (65 mm) and Leica (68 mm) microscopes.
- Straight and Sloped lens housing options available.
- Sloped lenses help to reduce the reflection of light that may disrupt the end users' vision.
- Sloped elastomer lens housing options are available.
- Elastomer material aids in gripping the microscope better; preventing the possibility of the lens housing from falling.

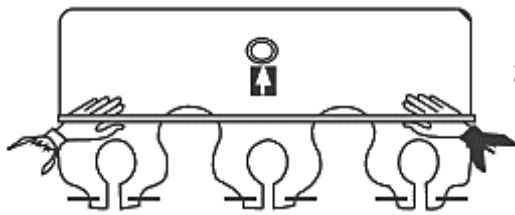
Intended for Use

It is used to cover surgical microscopes and to act as a physical barrier to prevent cross-contamination between the microscope and the patient/healthcare provider during the surgical procedure performed with the microscope.

Instructions for Use



- 1- Prepare Microscope by clamping all cables securely. Adjust tension of knobs.



- 2- Unfold drape, lens cover facing down and away from you, label up.



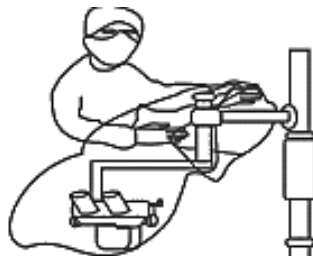
- 3- With hands placed inside center fold, form pouch opening.



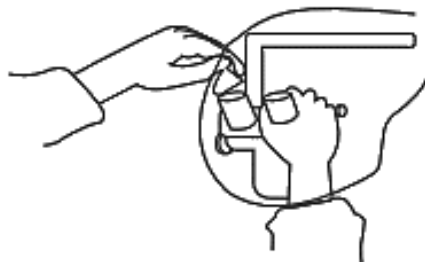
- 4- Feed drape over furthest protruding microscope components, continue unfolding drape over balance of microscope equipment.



- 5- Attach lens / light covers, applying upward pressure with palm of hand.

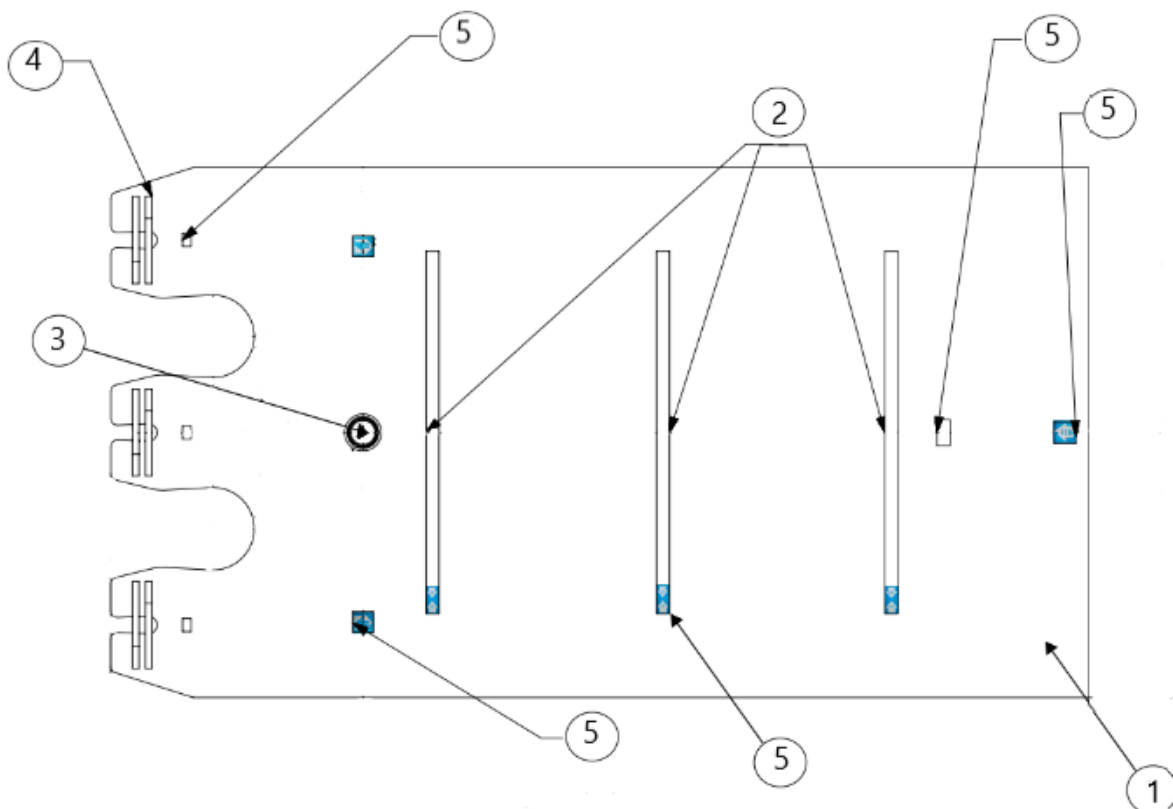


- 6- Extend balance of drape over microscope arm, gather up extra width with straps.



7 - Tighten excess material around eyepieces. Just before procedure remove top.

Technical Data



	Part	Qty	Material
1-	Cover/Drape	1	PE
2-	Belt	2-3	PE
3-	Core and Lens	1	Core: PE/PP, Lens:PC
4-	Adhesive Tape	6	PE
5-	Sticker	14-16	PE

Manufacturing Methods

- Injection
- Component Cutting
- Assembly
- Folding
- Packaging- Boxing
- EO sterilization

Specifications

- Sterilized by EO: Do not re-sterilize.
- Manufactured under ISO 13485 Quality Management System standard.
- CE certified under 2017/745 MDR.
- Latex free.
- Phthalate free.
- Medical device for single use Class Is: Do not reuse.

User Information

Storage:

Storage condition only valid for storing in original packaging. Do not use the product if the original packaging is damaged.

Storage temperature: Min:- Max: 28°C

Storage conditions: Keep away from direct sunlight
Keep dry

Packaging:

Packaging Unit: Packaging with single pouches

Box Qty: 60 pcs for smaller sizes and 50 pcs for larger sizes.

Regulatory Compliance:



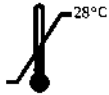
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STERILE EO

MD