



Surgical Microscope BIOM Lens

Workable with Image Inverter

Your Vision Is Our Mission



- High index accuracy;
- Large field of view;
- Making posterior segment surgery more perfect.

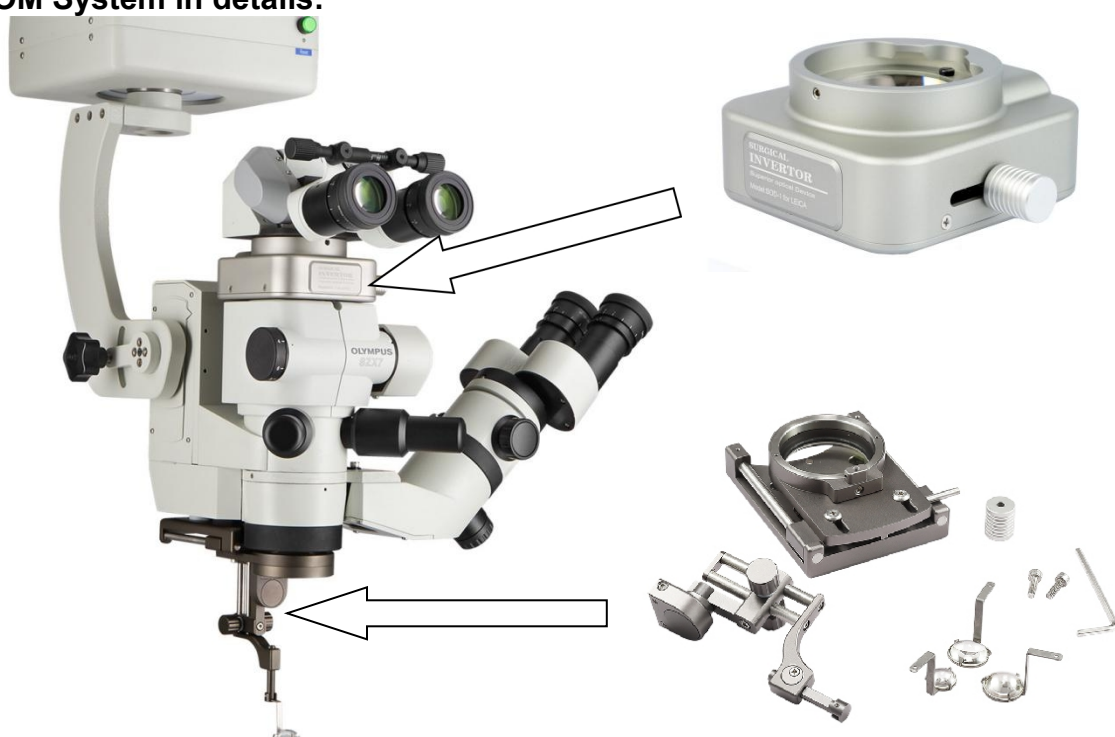
Technical Specifications

Lens	Field of View	Image Magnification	Lens Diameter
Big BIOM Lens	102°/120°	0.34X	19mm
Small BIOM Lens	95°/112°	0.42X	13mm
Medium BIOM Lens	80°/95°	0.74X	19mm

Related Matching Models

Brands	Models
Leica	M500, M501, M520, M620, M650, M651, M655, M690, M695, M820, M822, M840, M841, M844
Zeiss	Lumera, Lumera T, MDI, MDO, MDU, OPMI1, OPMI6, OPMI6-CFC, OPMI6S, OPMI6-SFC, OPMI6-SFR, OPMI6-CH, OPMIPico, OPMIVano, OPMIVISU 150, OPMIVISU 160, OPMIVISU 200, OPMIVISU 210
Topcon	OM 800 series, OMS 710, OMS 90
Moller-wedel	Hi-R 900
Takagi	OM-18
Alcon	LuxOR (Illumin-i)
Inami	L-0980A
Prescott	OMNI-FLEX
Huvitz	HOM-700

BIOM System in details:



Surgical Microscope Image Inverter

Model: VC-10M

CE Marked

Image Inverter is a kind of Adapter, used to put between Objective Lens and Eyepieces Lens of an Operating Microscope to provide an upright image for observer, when doing retinal vitreous surgery.

The image can be inverted by angle of 180°.

There is a thick metal stick to open and close inverting by moving up and down, without any focus adjustment. The operation is quite easy and convenient, even for beginners.

It is applicable in ZEISS, TOPCON, MOLLER, ALCON, TAKAGI, INAMI & LEICA etc. Ophthalmic Operating Microscopes.



Features:

- ✧ All durable iron materials;
- ✧ Anti-mildew and anti-moisture optical lens;
- ✧ Simple installation and operation, no focus adjustment;
- ✧ Compact and generous design;
- ✧ Light weight for easy carrying;
- ✧ Workable with BIOM Lens to meet different retinal vitreous surgery requirements.

Inverter used in Zeiss Surgical Microscopes:



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WhatsApp: 0086-13867435937



This is to certify that the Quality Management System of

Shanghai EDER Medical Technology Inc.

Unified Social Credit Code : 913101107032824702

Operation Address : No.42 Lane 328, Hengyong Road, Waigang Town, Jiading District, Shanghai, China(Production Address); Building 23, (Smart Bay Technology Park), No.6 Wenchuan Road, Baoshan District, Shanghai, China(Sales Address)

Registered Address : Room 712-8, Floor B, No.2, Lane 2005, Huangxing Road, Yangpu District, Shanghai, China

applicable to

Design, Development, Production and After-sales Services of Ophthalmic Surgical Microscopes, Surgical Microscopes(Within the Scope of License Qualification)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Managing Director



Certificate Number

45694

Date:

07 December 2018

Valid Until:

07 December 2021

EAC Code:

19





Documentation Review Report



No. 30171207.SEMQ097

Holder : Shanghai EDER Medical Technology Inc.
No. 42 Lane 328, Hengyong Rd. Jiading District,
Shanghai China

Review goal : Review of the Technical Documentation in
regards of the requirements of the
Medical Devices Directive 93/42/EEC Annex VII

Product : Surgical Microscope, Surgical Microscope
accessories

Surgical Microscope: EM-600A, EM-600B, SM-3000L,
SM-2000L, SM2000J, SM1000L, SM1000L/P

Model(s) : Surgical Microscope Accessories:
HD Video Adaptor, Remote Video Adaptor,
Video Adaptor for Camera, Beam Splitter,
HD Recorder, HD Camera, Surgical Invertor,
Non-contact lens Assembly

Classification : Class I
(accordingly to the Manufacturer's declaration)

Review output : The output of the Review of the Technical File
identified with the no. CE/MDD-2017/ (A0)
dated 2017-12-06 is that no Not-Conformity in
regards to the requirements of Directive
93/42/EEC Annex VII has been detected

Date of issue 07 December 2017

Expiry date 06 December 2022

Chief Manager
Marco Morina

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EC DECLARATION OF CONFORMITY

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Authorised EU Representative:

SUNGO Europe B.V.
Olympisch Stadion 24
1076DE Amsterdam
Netherlands

Declare under our sale responsibility that:

Product: Surgical Microscope, Surgical Microscope accessories

Type: see ANNEX

Classification: Class I

Rule: 12

Are in conformity with

Essential Requirements of European Directive

93/42/EEC

Medical Device Directive (including 2007/47/EC)

Standards:

EN ISO 14971: 2012

EN ISO 15223-1: 2016

EN 1041: 2008

ISO13485: 2016

ISO10936-1: 2006

Shanghai, China

12th October 2020

Hongbiao Zheng
Chairman



上海轶德医疗科技股份有限公司
Shanghai EDER Medical Technology Inc.



Name	Type
Surgical Microscope	EM-600A, EM-600B, SM-3000L, SM-2000L, SM2000J, SM1000L, SM1000L/P
Surgical Microscope Accessories	HD Video Adaptor, Remote Video Adaptor, Video Adaptor for Camera, Beam Splitter, HD Recorder, HD Camera, Surgical Invertor, Non - contact lens Assembly