



122/1 Smilyanska St., 18019 Cherkasy, Ukraine
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DECLARATION OF CONFORMITY

Manufacturer:	Science Engineering Center "Scanner" LLP 122/1 Smilyanska St., 18019 Cherkasy, Ukraine SRN: UA-MF-000049340	
Authorized representative:	AFINA, spol. s r.o. , Legal Address: Kaprova 42/14, 110 00, Prague, Czech Republic SRN: CZ-AR-000000584	
Product:	Microscope A medical device is designed for stereoscopic observation with optical magnification during examination and surgical interventions, postoperative examinations, dissection during medical research, training in courses, and has the ability to connect digital photo-video documentation devices.	
Model/Type:	MD-500	
Basic UDI-DI	482029653MDTX	
Classification of the device:	Class I, Annex VIII, Rule 13 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017	
Certificates:	Quality management system certificate in accordance with ISO 13485:2016 issued by Quality Austria Certification GmbH (registration number M-00223/0 valid until 26 February 2028) CB test certificate issued by UkrTEST of SE "Ukrmetrteststandart" (registration No.: UA-0206, UA-0207 issued 17 Oktober 2022)	
Meets the requirements:	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017	
Applicable standards:	EN 60601-1-1:2015; EN / IEC 60601-1-2:2018; EN / IEC 60601-1-6:2019; EN / IEC 61000-4-2:2018; EN / IEC 61000-4-3:2019; EN / IEC 61000-4-4:2022; EN / IEC 61000-4-5:2023; EN / IEC 61000-4-6:2019; EN / IEC 61000-4-11:2022; EN ISO 13485:2016; EN ISO 14971:2022; EN / IEC 55011:2019; EN / IEC 60529:2019; EN / IEC 62366:2019.	

We, the manufacturer hereby declare that the above-mentioned device complies with the relevant provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

The declaration of conformity is made under the single responsibility of the manufacturer.

Cherkasy 2025/11/11

Renat SINGATULLIN
Director





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ANNEX TO THE DECLARATION OF CONFORMITY

Components of the product Microscope MD-500

Catalog number	Name of component, assembly
65700A00	Stand
65600.03	Mobile base
-	Stationary base
64600A01	Ceiling mount
64600.01	Ceiling mount (with level adjustment)
62700.03	Wall mount
53500.00	Table mounting
64000.02	Tripod for mounting the monitor
65400.07	Power supply and balancing lever
65401.00	Power supply and balancing lever
65400M00	Power supply and balancing lever (Mora)
-	Power cord
65403100.01	Rotation joint
51800A01	Extension lever
6540501.00	Optical head bracket
65300.07	Optical head bracket
5010300V04	Optical head mount
60100.22	Optical head
60100A00	Optical head
60101.07	Optical head
50202D03	Lens f=200 mm (with fine focus)
50200D03	Lens f=250 mm (with fine focus)
50201D03	Lens f=300 mm (with fine focus)
50200G01	Lens f=350 mm
50201G01	Lens f=400 mm
54200.05	Variable lens 200 – 400 mm
53200.06	Variable lens 200 – 400 mm (with handle)
50800A05	Binocular piece $\pm 90^\circ$
60800.04	Binocular piece $\pm 90^\circ$ with axial rotation mechanism
50800V04	Binocular piece $\pm 90^\circ$ with axial rotation mechanism
60800B00	Binocular piece $\pm 90^\circ$ (for Mora)
20700.11	Binocular piece 45°
50600.06	Binocular piece 0°
50300B05	Eyepieces 12.5x
503005A.00	Eyecups for the eyepiece 12,5x
52300.00	Eyepieces 16x
503005.00	Eyecups for the eyepiece 16x
60300.01	Eyepieces 10x
-	Eyecups for the eyepiece 10x
5010400.06	Green light filter
5010401.05	Orange light filter
5010400A00	Orange light filter
5010401B00	Orange light filter
-	Natural light filter
50400A03	U-shaped handle
60116.00	T-shaped handle
54300.02	V-shaped handle
52100B07	Optical splitter 20/80
51100.06	Binocular adapter 45°

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Director



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Catalog number	Name of component, assembly
52100A06	0° adapter with 20/80 optical splitter for one channel
53701.00	Binocular adapter 45° with two channels optical splitter 20/80
53900B03	Binocular adapter 60° with optical splitter 20/80
63900A01	Binocular adapter 60° with optical splitter 20/80
63901A00	Binocular adapter 60° with optical splitter 20/80
63902A03	Binocular adapter 60° with optical splitter 20/80
53902V01	Binocular adapter 60° with optical splitter 20/80
65800.00	Mora adapter
-	Binocular assistant channel
62200.02	Photo adapter Sony
52900B05	Photo adapter Canon
52901B05	Photo adapter Nikon
53300A06	Video adapter Sony
54100A02	4D smartphone adapter
64100.03	4D smartphone adapter
-	Digital camera adapter
51200.09	Rotation binocular ring
52800B02	Lens protective glass
54400.00	Ring flash adapter
-	Assistant's monitor
54900.03	GoPRO adapter (with power supply)
64900.04	GoPRO adapter (GoPRO 7)
64900A09	GoPRO adapter (GoPRO 9)
55000.04	Mounting system and assistant monitor connection system
65000.03	Mounting system and assistant monitor connection system
55100.03	Mounting system and tablet monitor connection system
65100.05	Mounting system and tablet monitor connection system
50143.00	Silicone cap for shifting magnification knob
54712.00	Silicone cap for small force adjustment knob
53122.00	Silicone cap for large force adjustment knob
54508.00	Silicone cap for handle to adjust illuminator brightness
54304.00	Silicone cap for V-shaped handle
50405.00	Silicone cap for U-shaped handle
54208.00	Silicone ring for variable lens
53214.00	Silicone cap for variable lens handle
-	Automatic lighting control system "Smart light"
601112.01	Additional florescent source of light "Fluorescent light"
-	Device for transmitting images via Wi-Fi
51200V00	Zeiss

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Director

