



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:	Colposcope A medical device intended for stereoscopic observation with optical magnification by a non-contact method of the vagina, cervix and lower third of the cervical canal during gynecological and oncogynecological examinations.
Model/Type:	MK-200 MK-300
Basic UDI-DI	482029653MKUD
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)
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 ISO 13485:2016; EN / IEC 60601-1-2:2018; EN ISO 14971:2022; EN / IEC 60601-1-6:2019; EN / IEC 55011:2019; EN / IEC 61000-4-2:2018; EN / IEC 60529:2019; EN / IEC 61000-4-3:2019; EN / IEC 62304:2019; EN / IEC 61000-4-4:2022; EN / IEC 62366:2019. EN / IEC 61000-4-5:2023; EN / IEC 61000-4-6:2019; EN / IEC 61000-4-11:2022;

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

Director
Renat SINGATULLIN





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ANNEX TO THE DECLARATION OF CONFORMITY

Components of the product Colposcope MK-200

Catalog number	Name of component, assembly
70601.00	Stand
7160101.00	Laptop stand
71602.01	Mobile base
72600.02	Tripod for monoblock
20900.00	Chair mount tripod
70800A07	Power supply and balancing lever
-	Power cord
70700.02	Laptop shelf
21000.00	Bracket for mounting the monitor
74700.10	Optical head bracket
70100.05	Optical head
20202V02	Lens f=200 mm (with fine focus)
20200V02	Lens f=250 mm (with fine focus)
20201V03	Lens f=300 mm (with fine focus)
50200G01	Lens f=350 mm
53200.06	Variable lens 200 – 400 mm (with handle)
64200.00	Variable lens 200 – 400 mm
70500.01	Binocular piece 45°
50300B05	Eyepieces 12.5x
503005A.00	Eyecups for the eyepiece 12,5x
52300.00	Eyepieces 16x
503005.00	Eyecups for the eyepiece 16x
-	Eyepieces 10x
-	Eyecups for the eyepiece 10x
20900B12	Colposcope video system MK-200
-	Colposcope video system MK-200
70900.04	Colposcope video system MK-200

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Director





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Components of the product Colposcope MK-300

Catalog number	Name of component, assembly
30100U00	Colposcope head
30600U00	Tripod floor
30500U01	Power supply unit
-	Power cord
30800V07	Colposcope video system MK-300
30800U01	Colposcope video system MK-300

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