



DECLARATION OF CONFORMITY

ACCORDING TO In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands

SRN: NL-AR-000000247

Device Classification

Classification: Class A.

Rule: According to Rule 5, Annex VIII, of
In Vitro Diagnostic Medical Devices
Regulation (EU)2017/746.

Applicable Standards

EN ISO 20417: 2021,
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 14971:2019
EN ISO 18113-3:2011
EN 55032:2015+A1:2020
EN 55035:2017+A11:2020

Manufacturer

Name: Motic China Group Co., Ltd.

Address: No 810 Fangshan Nan Road, XiangAn,
Xiamen 361100, P.R. China

SRN: CN-MF-000033671

Product Information

Name: Camera

Model: Moticam A1

Moticam A2

Moticam A5

Moticam A8

Moticam A16

Moticam S1

Moticam S3

Moticam S6

Moticam S6 MONO

Moticam S12

Moticam S20

Moticam Pro S5 Lite

Moticam Pro S5 Plus

Moticam X5 Plus

Moticam BTI

EMDN: W0202050380

Basic UDI-DI: 697396716 CameraJ2

Classification: Class A



Conformity Assessment

Compliance of the designated product with the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 has been assessed by issuing the EU declaration of conformity referred to in Article 17 after drawing up the technical documentation set out in Annexes II and III.

Remark

The declaration of conformity is valid in connection with the release technical document CE/IVDR-W0202050380-03.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Declaration

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 and the applicable standards above.

Signature:

Date: Jan 6th, 2025

Full Name: Wong Jui Sin

Position: CEO

Place: Fujian/China





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EU Representative

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Fascinatio Boulevard 522, Unit 1.7,
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Netherlands
SRN: NL-AR-000000247

Device Classification

Classification: Class A.
Rule: According to Rule 5, Annex VIII, of
In Vitro Diagnostic Medical Devices
Regulation (EU)2017/746.

Applicable Standards

EN ISO 20417: 2021
EN ISO 15223-1:2021
EN ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-3:2011
EN 61010-1:2010+A1:2019
IEC 61326-1-2015+A1:2020
IEC 61326-2-6:2017

Manufacturer

Name: Motic China Group Co., Ltd.
Address: No 810 Fangshan Nan Road, XiangAn,
Xiamen 361100, P.R. China
SRN: CN-MF-000033671

Product Information

Name: Biological Microscope
Model: Panthera E2, Panthera C2, Panthera DL,
Panthera Cloud, PA43, PA53 BIO, BA210E,
BA210LED, BA310E, BA310LED, BA410E 50W,
BA410E 100W
EMDN: W0202050301
Basic UDI-DI: 697396716Microscope001BG
Classification: Class A

Conformity Assessment

Compliance of the designated product with the In
Vitro Diagnostic Medical Devices Regulation
(EU)2017/746 has been assessed by issuing the EU
declaration of conformity referred to in Article 17 after
drawing up the technical documentation set out in
Annexes II and III.



Remark

The declaration of conformity is valid in connection with the release technical document CE/IVDR-W0202050301-02.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Declaration

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 and the applicable standards above.

Signature:

Date: Jan 6th, 2025

Full Name: Wong Jui Sin

Position:

CEO 奥迪实业
集团有限公司

Place: Fujian/China



Certificate CN05/00178
CN Number F00126Q00523R702

The management system of

Motic China Group Co., Ltd.

SGS

Unified Social Credit Code: 91350200612018359W

Business Registration Address: No. 810 Fangshan Nan Road, Torch Hi-Tech Zone, Xiang'an District, Xiamen

Business Operation Address: No. 810 Fangshan Nan Road, Torch Hi-Tech Zone, Xiang'an District, Xiamen, Fujian Province, P.R. China

has been assessed and certified as meeting the requirements of

ISO 9001:2015

Quality management systems - Requirements

For the following activities

Design and manufacture of optical microscopes and digital microscopes

This certificate is valid from 07 April 2026 until 06 April 2029 and remains valid subject to satisfactory surveillance audits.

Issue 10. Certified since 07 April 2005

L. Moran

Authorised by

Liz Moran

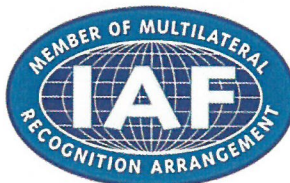
Business Manager

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com

The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn



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UKCA DECLARATION OF CONFORMITY



We, Motic China Group Co., Ltd.

Declare that the product,

Microscope Model(s):

Panthera C2 Series

We take full responsibility for the product's compliance on:

Electrical Equipment (Safety) Regulations 2016

Standards to which conformity is declared:

BS EN 61010-1: 2010 Safety requirements for electrical equipment for measurement, control and laboratory use.
Part 1: General requirements

Electromagnetic Compatibility Regulations 2016

Standards to which conformity is declared:

BS EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.
EN 61326-2-2:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-2: Particular requirements - Test configurations, operational conditions and performance criteria for portable test, measuring and monitoring equipment used in low-voltage distribution Systems.
EN 61000-3-2:2018 Electromagnetic compatibility (EMC)-Part 3-2: Limits for harmonic current emissions (equipment input current ≤16 A per phase)
EN 61000-3-3:2013 Electromagnetic compatibility (EMC)-Part 3: Limits-Section 3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection

Manufacturer: Motic China Group Co., Ltd.

Address: Motic building Torch Hi-Tech Industrial Development Zone, Xiamen, Fujian, 361006 China.

Tel: (592) 5627866

Fax: (592) 5627855

Email: info@motic.com

Signature:

A handwritten signature in black ink, appearing to be 'Zhihe Zhang', written over a horizontal line.

Name: Zhihe Zhang (Quality Manager)

Date: 13 September 2023



More Than Microscopy

DECLARATION OF CONFORMITY

**We, Motic China Group Co., Ltd.
No 810 Fangshan Nan Road, XiangAn**

Xiamen, Fujian, 361101, China

Declare that the product:

Microscope Model: Panthera C2

Is in conformity with

Council Directive 2014/30/EU (EMC Directive)

Standards to which conformity is declared

EN 61326-1:2021

Electrical equipment for measurement, control and laboratory use - EMC requirements
- Part 1: General requirements

EN 61326-2-2:2021

Electrical equipment for measurement, control and laboratory use - EMC requirements
- Part 2-2: Particular requirements - Test configurations, operational conditions and performance criteria for portable test, measuring and monitoring equipment used in low-voltage distribution systems

EN 61000-3-2:2019

Electromagnetic compatibility (EMC)-Part 3-2:Limits for harmonic current emissions
(equipment input current ≤ 16 A per phase)

EN 61000-3-3:2013

Electromagnetic compatibility (EMC)-Part 3:Limits-Section 3:Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated currents ≤ 16 A per phase and not subject to conditional connection

Manufacturer:

Motic China Group Co., Ltd.

Signature:

Name:

Zhihe Zhang(Group Quality Manager)

Date:

27-April-2026

**Address: No 810 Fangshan Nan Road, XiangAn,
Xiamen, Fujian, 361101, China.**

Tel: (592) 5627866

Fax: (592) 5627855

Email: info@motic.com

DECLARATION OF CONFORMITY

**We, Motic China Group Co., Ltd.
No 810 Fangshan Nan Road, XiangAn**

Xiamen, Fujian, 361101, China

Declare that the product:

Microscope Model: Panthera C2

Is in conformity with

Council Directive 2014/35/EU (Low Voltage Directive)

Standards to which conformity is declared

EN 61010-1: 2010

Safety requirements for electrical equipment for
measurement, control and laboratory use.
Part 1: General requirements

Manufacturer:

Motic China Group Co., Ltd.

Signature:



Name:

Zhihe Zhang(Group Quality Manager)

Date:

27-April-2026

Address:

**No 810 Fangshan Nan Road, XiangAn,
Xiamen, Fujian, 361101, China.**

Tel: (592) 5627866

Fax: (592) 5627855

Email: info@motic.com

EC Declaration of Conformity

We, the undersigned

Applicant: MOTIC CHINA GROUP Co., Ltd
Address, City: Motic BLDG, TORCH HI-TECH INDUSTRIAL DEV ZONE, XIAMEN FUJIAN
Country/Region: CHINA
Manufacturer: MOTIC CHINA GROUP Co., Ltd
Address, City: Motic BLDG, TORCH HI-TECH INDUSTRIAL DEV ZONE, XIAMEN FUJIAN
Country/Region: CHINA

certify and declare under our sole responsibility that the following product(s):

EUT Description: Motic 4K Camera
Brand/Trade Mark: N/A
Model: Moticam 4000, BMH4000
Rating : 12V=== 1A
(AC/DC SWITCHING ADAPTOR: Input: 100-240VAC, 50/60Hz, 0.3A max;
Output: 12V=== 1A)

conforms with the essential requirements of the EMC Directive 2014/30/EU, based on the following standard(s) applied:

EN 55032:2015+A11:2020
EN 55035:2017+A11:2020
EN IEC 61000-3-2:2019
EN 61000-3-2:2014
EN 61000-3-3:2013+A1:2019

and therefore compiles with essential requirements and provisions of the EMC Directive. Further information refers to Technical Documentation kept by manufacturer or authorized representative. The CE mark can be affixed on the product(s) by declarer when other applicable directives also are observed.

☐ Manufacturer
☐ Authorized representative
Name:
Title:
Signature:

T/R No.: S20211013513901 **Test Laboratory**
DoC No.: CS20211013513901



Fangguang Inspection & Testing Co., Ltd.



Signature: Connie Yang

Date: _____

Date: November 2, 2021



Verification of Conformity

Registration No.:A2312080-C01-E01

Report No. : A2312080-C01-R01, A2312080-C01-R04, A2312080-C01-R05,
A2312080-C01-R06, A2312080-C01-R07, A2312080-C01-R08

Applicant : Motic China Group Co., Ltd.

Address : No 810 Fangshan Nan Road, XiangAn, Xiamen 361101, P.R. China

Product : Moticam

Model No. : Moticam 4000X, Moticam 4000X BMH

The submitted products have been tested by us with the listed standards and found in compliance with the following European Directives:

The Radio Equipment Directive (RED) 2014/53/EU

EN IEC 62368-1:2020+A11:2020

ETSI EN 301 489-1 V2.2.3:2019

ETSI EN 301 489-3 V2.3.2:2023

ETSI EN 301 489-17 V3.2.4:2020

ETSI EN 300 328 V2.2.2:2019

ETSI EN 301 893 V2.1.1:2017

ETSI EN 300 440 V2.2.1:2018

EN IEC 62311:2020

The test results apply only to the particular sample tested and to the specific tests carried out. This verification applies specifically to the sample investigated in our test reference number only.



Certified by:

Reak Yang

Date:

March 29, 2024



Shenzhen Alpha ProductTesting Co., Ltd.

Building i, No.2, Lixin Road, Fuyong Street, Bao'an District, 518103, Shenzhen City, Guangdong Province, P.R. China

Website: <http://www.a-lab.cn>

Email: service@a-lab.cn

The CE marking may only be used if all relevant and effective EC directives are complied with.

ALPHA



Website



WeChat