



EC Declaration of Conformity

We, the manufacturer, Carl Zeiss Suzhou Co., Ltd. Modern Industrial Square 3-B, No.333, XingPu Road SIP, 215126 Suzhou, China(SRN: CN-MF-000017606), declare under our sole responsibility that the product mentioned below is in conformity with the requirements of the following regulation and directives:

- (EU) 2017/ 746 on in vitro diagnostic medical devices of April 5, 2017.
- 2011/ 65/ EU of June 8, 2011 and (EU) 2015/ 863 of March 31, 2015, on the restriction of the use of hazardous substances in electrical and electronic equipment

Authorised representative: Carl Zeiss Microscopy GmbH, Carl Zeiss Promenade 10, 07745 Jena, Germany

Any modification to the product, not authorized by us, will invalidate this declaration.

Product identification:

Upright Microscope

Trade name:

Axioscope 5

with accessories

Upright microscope system to visualize samples derived from the human body

Standards:

EN 61010-1:	2019
EN 61010-2-101:	2017
EN IEC 61326-1:	2021
EN IEC 61326-2-6:	2021
EN IEC 63000:	2018

Risk Class according to Annex VIII (EU) 2017 / 746:

A

Basic-UDI-DI according to Annex VI (EU) 2017 / 746:

6909262CNA003QD

Conformity Assessment According to:

Annex II and III (EU) 2017 / 746

RoHS-conform with Exception:

6a, 6a-I, 6b, 6b-I, 6b-II, 6c, 7a, 7c-I, 13a

Basis - Record of Conformity No.:

KC-MIK11-0236, Version 03

Registered:

CZSZ MIC CE 005-2022

The product is marked with



Date: **Suzhou, 13.07.2023**

Lei Xie
General Manager
Carl Zeiss Suzhou Co., Ltd.

Jian Shu Wang
Person responsible
acc. Article 15 (EU) 2017/ 746
Carl Zeiss Suzhou Co., Ltd.