

## **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, 2011and (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:

Inverted microscope

Trade name:

Axio Vert.A1

with accessories

Inverted microscope system to visualize samples derived from the human body

Standards:

EN 61010-1: 2019

EN 61010-2-101: 2017 2013

EN 61326-1: EN 61326-2-6:

EN IEC 63000:

2013 2018

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

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

6909262CNA002QB

Conformity Assessment According to:

Annex II and III (EU) 2017 / 746

RoHS-conform with Exception:

6c, 7a, 7c, 7c-I

Basis - Record of Conformity No.:

KC-MIK12-0043, Version 02

Registered:

CZSZ MIC CE 003-2022

The product is marked with CE

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.

Conditions of guarantee and liability are dealt within our General Conditions of Sale