



EU 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:

Inverted microscope

Trade Name:

Primover
with accessories

Inverted microscope system to visualize samples derived from the human body

Standards:

EN 61010-1:	2019
EN 61010-2-101:	2017
EN 61326-1:	2013
EN 61326-2-6:	2013
EN IEC 63000 :	2018

Risk class according to Annex VIII (EU) 2017 / 746:
Basic-UDI-DI according to Annex VI (EU) 2017 / 746:
Conformity Assessment according to:
RoHS-conform with exception:
Basis – Record of Conformity No.:
Registered:

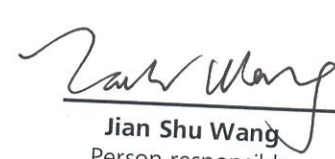
A
6909262CNA002QB
Annex II and III (EU) 2017 / 746
6a, 6b, 6b-I, 6b-II, 6c, 7a, 7c-I
KC-MIK5-0104, Version 02
CZSZ MIC CE 002-2022

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.

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