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: **Primovert**

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:	A
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:	6a, 6b,6b-I,6b-II,6c,7a,7c-I
Basis – Record of Conformity No.:	KC-MIK5-0104, Version 02
Registered:	CZSZ MIC CE 002-2022

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.