# EC Declaration of Conformity

In Accordance with EC Directive 98/79/EEC on in-vitro diagnostic medical devices

**Manufacturer:** **Carl Zeiss Suzhou Co.,Ltd., Modern IndustrialSquare 3-B, No. 333, XingPu Road, SIP, 215126, Suzhou, China.**
(Quality Management System certified to meet: ISO 9001:2008, ISO 13485:2003)
(Environmental Management System certified to meet: ISO 14001:2004 + Cor 1:2009)

**EU Representative:** **Carl Zeiss Microscopy GmbH, Carl-Zeiss-Promenade 10, 07745 Jena, Germany**

We, Carl Zeiss Suzhou Co.,Ltd, declare the compliance of the device with the products of the **Council Directive 98/79/EEC on In-vitro-Diagnostic Medical Device** and with the **Directive 2011/65/EU of European Parliament and of the Council of June 08 2011 on the Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)**.

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

**Product identification:** **Microscopes**

**Device Trade Name:** **Primo Star, Primo Star iLED**

**In-Vitro diagnostic Medical Device Class:** **General/Other**
**IVDD 98/79/EC**

**Conformity Assessment Procedure: According to Annex I & Annex III of IVDD 98/79/EC**

**Standards:**

| | |
|---|---|
| EN 61010-1: | 2010 |
| EN 61010-2-101: | 2002 |
| EN 61326-1: | 2013 |
| EN 61326-2-6: | 2013 |
| EN 50581: | 2012 |

RoHS-conform with exception: **6c** (Status 2014-12-18)

The product is marked with CE.

**Carl Zeiss Suzhou Co.,Ltd**
Suzhou, 2016-03-08

Lei, Xie
General Manager

Xiaodong, Huang
Representive of Quality Management