Declaration of Conformity

Manufacturer:	**Caretium Medical Instruments Co., Limited** **Beishan Industrial Park 7th Floor Building 1,Beishan Road Yantian,Shenzhen 518083 China**
European Representative:	**Prolinx GmbH** **Brehmstr. 56, 40239, DÜesseldorf, Germany**
Product Name:	**Automated ESR Analyzer**
Models:	XC-A30,XC-A10

Classification (98/79/EC IVDD, Annex II): **Other**

Conformity Assessment Route: **Annex III**

We herewith declare under our sole responsibility that the above mentioned products meet IVDD 98/79/EC. All supporting documentations are retained under the premises of the manufacturer.

General applicable directive and standards:
Medical Device Directive: COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning In Vitro Diagnostic Medical Devices (IVDD 98/79/EC).
Applied EN standards:
EN ISO 13485:2012/AC:2012, EN ISO 14971:2012, EN 61010-1:2010, EN 61010-2-101:2013, EN 61010-2-081:2002, EN ISO 17511: 2003, EN 13641: 2002, EN 62366:2008, EN 15223-1: 2016, EN 1041:2008.EN 61326-1:2013，EN ISO 18113-1:2011

Shenzhen, 2019-02-01

Place, Date of Issue:

Signature:

Name: **Shoufu Li**

Position: **General Manager**