

DECLARATION OF CONFORMITY

We, the manufacturer:

Chongqing Bio NewVision Medical Equipment Ltd.

Address: #1-10, Floor 9th of building #4, Group 2N of 2nd Project,
Fulicheng Zhihuiguoji, Shapingba District, 401331 Chongqing,
PEOPLE'S REPUBLIC OF CHINA

Tel: +86 023-65456668

Fax: +86023-65456669

EU Representative: SUNGO Europe B.V.

VAT: NL857821659B01

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Contact: SUNGO Secretary

Tel: +31(0) 2 021 11106

Fax: +31(0) 2 021 11106

E-mail: ec.rep@sungogroup.com

Declare under our sole responsibility that:

Product: **Biometer**

Model Name: **AL-View**

Product Group: **Ophthalmic Equipment**

Classification: **Class I** (in compliance with Annex VII, Medical Device Directive)

Are in conformity with:

Essential Requirements of European Directive(s):

Medical Device Directive 93/42/EEC

Standard(s):

IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012 AAMI/ANSI/ES 60601-1:2012

IEC 60601-1-2:2014

ISO 10993-5:2009

ISO 10993-10:2010

ISO 10940:2009

ISO 15004-1:2006

ISO 15004-2:2007

EN 62304:2006

EN 62366:2008

ISO 13485:2016



Signature: Robert Wang

Export Sales Manager

2019-06-01