

Current Date: 2025-01-16

To:

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

No. 588 West Jindu Road, Songjiang District, Shanghai, China. 201612

Dear Sir/Madam,

Subject: **Declaration Letter about Identity of Products***WE (Shanghai MediWorks Precision Instruments CO., Ltd.) HEREBY DECLARED THAT

Product Description	Optical Biometer
Model No.	AL551, AL552
Manufacturer's Name	Shanghai MediWorks Precision Instruments CO., Ltd.
Manufacturer's Address	No.7, Ming Pu Phase 2, No. 3279 San Lu Road, Min Hang District, 20110, Shanghai, China

*Except that below differences, other are identical with the original product as follows:

Only difference is AL551 and AL 552 have fewer software functions compared to AL 550.

Model Performance Indicator		AL550	AL551	AL552
Axial length measurements		Applicable	Applicable	Applicable
Corneal thickness measurements		Applicable	Applicable	Not applicable
Anterior chamber depth measurements		Applicable	Applicable	Not applicable
Lens thickness measurements		Applicable	Applicable	Not applicable
Corneal topography	Area measurements	Applicable	Applicable	Not applicable
	Sample density measurement	Applicable	Applicable	Not applicable
	Performance measurements and reports	Applicable	Applicable	Not applicable
	Results shown in colors	Applicable	Applicable	Not applicable
Radius of curvature measurements		Applicable	Applicable	Applicable
Measurement of main meridian axial position		Applicable	Applicable	Applicable
Pupil diameter measurement range		Applicable	Applicable	Applicable
White to white measurement range		Applicable	Applicable	Applicable
Projection ring diameter		Applicable	Applicable	Not applicable

Software Features				
Settings	General	Applicable	Applicable	Applicable
	Date and time	Applicable	Applicable	Applicable

Shanghai MediWorks Precision Instruments CO., Ltd.

	Network	Applicable	Applicable	Applicable
	Report	Applicable	Applicable	Applicable
	Capture	Applicable	Applicable	Applicable
	Corneal topography	Applicable	Applicable	Not applicable
	DICOM	Applicable	Applicable	Applicable
	Refractive index	Applicable	Applicable	Applicable
	RGP management	Applicable	Applicable	Not applicable
	Accounts	Applicable	Applicable	Applicable
	Storage	Applicable	Applicable	Applicable
	About	Applicable	Applicable	Applicable
Patient information management	Add patients	Applicable	Applicable	Applicable
	View patients	Applicable	Applicable	Applicable
	Edit patients	Applicable	Applicable	Applicable
Medical case management	Create new medical cases	Applicable	Applicable	Applicable
	Delete medical cases	Applicable	Applicable	Applicable
	View medical cases	Applicable	Applicable	Applicable
Capture	Automatic image data capture	Applicable	Applicable	Applicable
	Manual image data capture	Applicable	Applicable	Applicable
Corneal topography and axial measurement	Overview	Applicable	Applicable	Applicable
	Topographic maps	Applicable	Applicable	Not applicable
	Four maps	Applicable	Applicable	Not applicable
	Shape factor	Applicable	Applicable	Not applicable
	Zernike	Applicable	Applicable	Not applicable
	RGP	Applicable	Applicable	Not applicable
	Pupil & Cornea	Applicable	Applicable	Applicable
	Axial measurement	Applicable	Applicable	Applicable
	IOL calculation	Applicable	Not applicable	Not applicable
	Comparison	Applicable	Applicable	Applicable
	Report	Applicable	Applicable	Applicable

Note: The definition of identical should be “**electrically identical**”. A device will be considered to be electrically identical if no changes are made to the devices’ schematics, board layouts, component layouts, chip sets, resistors and all other electrical aspects of the device are identical.

Shanghai MediWorks Precision Instruments CO., Ltd.

Model No.:	AL550
Manufacturer's Name:	Shanghai MediWorks Precision Instruments CO., Ltd.
Manufacturer's Address:	No.7, Ming Pu Phase 2, No. 3279 San Lu Road, Min Hang District, 20110, Shanghai, China

Sincerely,

Signature:	
Printed Name:	Weida Zhan
Position/Title:	Management Representative
Contact Number:	13681849376