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

<sup>\*</sup>Except that <u>below differences</u>, 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	Axial length measurements		Applicable	Applicable
Corneal thickness measurements		Applicable	Applicable	Not applicable
Anterior chamber depth measurements		Applicable	Applicable	Not applicable
Lens thickness measurements		Applicable	Applicable	Not applicable
	Area measurements	Applicable	Applicable	Not applicable
Corneal	Sample density measurement	Applicable	Applicable	Not applicable
topography	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				
Sattings	General	Applicable	Applicable	Applicable
Settings	Date and time	Applicable	Applicable	Applicable

Shanghai MediWorks Precision Instruments CO., Ltd.

Network   Applicable   Applic		- Changhai Wedivverks i reel		I	
Capture Applicable Applicable Applicable Applicable DICOM Applicable Applicab		Network	Applicable	Applicable	Applicable
Corneal topography Applicable Applicable Applicable Applicable  DICOM Applicable Applicable Applicable Applicable  Refractive index Applicable Applicable Applicable  Refractive index Applicable Applicable Applicable  RGP management Applicable Applicable Applicable  Accounts Applicable Applicable Applicable Applicable  Accounts Applicable Applicable Applicable Applicable  About Applicable Applicable Applicable Applicable  About Applicable Applicable Applicable Applicable  Add patients Applicable Applicable Applicable  View patients Applicable Applicable Applicable Applicable  Medical case Medical cases Applicable Applicable Applicable Applicable  Create new medical cases Applicable Applicable Applicable  Delete medical cases Applicable Applicable Applicable  View medical cases Applicable Applicable Applicable  View medical cases Applicable Applicable Applicable  Automatic image data capture Applicable Applicable Applicable  Topographic maps Applicable Applicable Applicable Applicable  Topographic maps Applicable Applicable Applicable Not applicable  Four maps Applicable Applicable Not applicable  RGP Applicable Applicable Applicable Not applicable  RGP Applicable Applicable Applicable Applicable Not applicable  Axial measurement Applicable Applic		Report	Applicable	Applicable	Applicable
DICOM Applicable Applicable Applicable Refractive index Applicable Applicable Not applicable Accounts Applicable Applicable Applicable Applicable About Applicable Applicable Applicable Applicable About Applicable Applicable Applicable Applicable Add patients Applicable Applicable Applicable View patients Applicable Applicable Applicable Edit patients Applicable Applicable Applicable Create new medical cases Applicable Applicable Applicable Delete medical cases Applicable Applicable Applicable View medical cases Applicable Applicable Applicable Not applicable Applicable Applicable Not applicable RGP Applicable Applicable Applicable Applicable Applicable Pupil & Cornea Applicable Applicable Applicable Not applicable Axial measurement Applicable Not applicable Not applicable Axial measurement Applicable Not applicable Not applicable Comparison Applicable Applicable Applicable Not applicable		Capture	Applicable	Applicable	Applicable
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RGP management Applicable Applicable Applicable Accounts Applicable Applicable Applicable Storage Applicable Applicable Applicable About Applicable Applicable Applicable Applicable Applicable Applicable Edit patients Applicable Applicable Applicable Edit patients Applicable Applicable Applicable Delete medical cases Applicable Applicable Applicable View medical cases Applicable Applicable Applicable View medical cases Applicable Applicable Applicable View medical cases Applicable Applicable Applicable Automatic image data capture Applicable Applicable Applicable Applicable Applicable Applicable Applicable Four maps Applicable Applicable Not applicable Four maps Applicable Applicable Not applicable Shape factor Applicable Applicable Not applicable RGP Applicable Applicable Not applicable Axial measurement Applicable Applicable Applicable Applicable Not applicable Axial measurement Applicable Applic		DICOM	Applicable	Applicable	Applicable
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Storage Applicable Applicable Applicable About Applicable Applicable Applicable About Applicable Applicable Applicable Add patients Applicable Applicable Applicable Information Management  Edit patients Applicable Applicable Applicable Edit patients Applicable Applicable Applicable  Create new medical cases Applicable Applicable Applicable Delete medical cases Applicable Applicable Applicable View medical cases Applicable Applicable Applicable View medical cases Applicable Applicable Applicable  Automatic image data capture Applicable Applicable Applicable  Capture Manual image data capture Applicable Applicable Applicable  Overview Applicable 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 Applicable Not applicable  Axial measurement Applicable Applicable Applicable Applicable  IOL calculation Applicable Applicable Not applicable Comparison Applicable Applicable Applicable Not applicable Axial measurement Applicable App		RGP management	Applicable	Applicable	Not applicable
About Applicable Applicable Applicable Applicable Patient information management  Medical case management  Capture  Capture  Corneal topography and axial measurement  Comparison  Add patients  Add patients  Applicable  Applicable A		Accounts	Applicable	Applicable	Applicable
Patient information Wiew patients Applicable		Storage	Applicable	Applicable	Applicable
information management  View patients  Applicable  App		About	Applicable	Applicable	Applicable
management Edit patients Applicable Applicable Applicable  Create new medical cases Applicable Applicable Applicable  Delete medical cases Applicable Applicable Applicable  View medical cases Applicable Applicable Applicable  Capture Applicable Applicable Applicable Applicable  Automatic image data capture Applicable Applicable Applicable  Manual image data capture Applicable Applicable Applicable  Topographic maps Applicable Applicable Not applicable  Four maps Applicable Applicable Not applicable  Shape factor Applicable Applicable Not applicable  Corneal topography and axial measurement  RGP Applicable Applicable Applicable Not applicable  Applicable Applicable Applicable Not applicable  Applicable Applicable Applicable Not applicable  Applicable Applicable Applicable Applicable Not applicable  Axial measurement Applicable Applicable Applicable Applicable  Axial measurement Applicable Applicable Applicable Applicable Applicable  Comparison Applicable Applicable Not applicable Not applicable  Applicable Ap	Patient	Add 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  Overview Applicable Applicable Applicable Applicable  Topographic maps Applicable Applicable Not applicable  Four maps Applicable Applicable Not applicable  Shape factor Applicable Applicable Not applicable  Corneal topography and axial measurement  RGP Applicable Applicable Applicable Not applicable  Applicable Applicable Applicable Not applicable  Applicable Applicable Applicable Applicable Not applicable  Axial measurement Applicable Applicable Applicable Applicable  Comparison Applicable Applicable Not applicable	information	View patients	Applicable	Applicable	Applicable
Medical case management  Delete medical cases Applicable	management	Edit patients	Applicable	Applicable	Applicable
Delete medical cases		Create new medical cases	Applicable	Applicable	Applicable
View medical cases Applicable Applicable Applicable  Automatic image data Applicable Applicable Applicable  Applicable Applicable Applicable Applicable  Applicable Applicable Applicable Applicable  Overview Applicable Applicable Applicable  Topographic maps Applicable Applicable Not applicable  Four maps Applicable Applicable Not applicable  Shape factor Applicable Applicable Not applicable  Shape factor Applicable Applicable Not applicable  Shape factor Applicable Applicable Not applicable  RGP Applicable Applicable Not applicable  RGP Applicable Applicable Applicable Applicable  Axial measurement Applicable Applicable Applicable  Axial measurement Applicable Applicable Applicable  Comparison Applicable Applicable Not applicable  Applicable Applicable Applicable  Applicable Applicable Applicable  Applicable Applicable Applicable  Applicable Applicable Applicable		Delete medical cases	Applicable	Applicable	Applicable
Capture Capture Applicable Applicable Applicable Applicable  Manual image data capture Applicable Applicable Applicable Applicable  Overview Applicable Applicable Applicable Applicable  Topographic maps Applicable Applicable Not applicable  Four maps Applicable Applicable Not applicable  Shape factor Applicable Applicable Not applicable  Corneal topography and axial measurement  Manual image data capture Applicable Applicable Not applicable  Applicable Applicable Not applicable  RGP Applicable Applicable Not applicable  Applicable Applicable Applicable Applicable  Axial measurement Applicable Applicable Applicable  IOL calculation Applicable Applicable Not applicable  Comparison Applicable Applicable Applicable Applicable  Applicable Applicable Applicable Applicable	management	View medical cases	Applicable	Applicable	Applicable
Overview Applicable Applicable Applicable Topographic maps Applicable Applicable Not applicable Four maps Applicable Applicable Not applicable Shape factor Applicable Applicable Not applicable Topography and axial measurement  Mathematical Pupil & Cornea Applicable Applicabl	Capture	C	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  topography and axial measurement  RGP Applicable Applicable Not applicable  Applicable Applicable Applicable Applicable  Applicable Applicable Applicable Applicable  Axial measurement Applicable Applicable Applicable  IOL calculation Applicable Not applicable  Comparison Applicable Applicable Applicable Applicable  Applicable Applicable Applicable Applicable  Applicable Applicable Applicable Applicable		Manual image data capture	Applicable	Applicable	Applicable
Four maps Applicable Applicable Applicable Not applicable Corneal topography and axial measurement  Pupil & Cornea Applicable		Overview	Applicable	Applicable	Applicable
Shape factor Applicable Applicable Not applicable  Corneal Zernike Applicable Applicable Not applicable topography and axial measurement Pupil & Cornea Applicable IOL calculation Applicable Not applicable Not applicable Comparison Applicable		Topographic maps	Applicable	Applicable	Not applicable
Corneal topography and axial measurement Pupil & Cornea Applicable IOL calculation Applicable Applicable Applicable Applicable Applicable Comparison Applicable		Four maps	Applicable	Applicable	Not applicable
topography and axial measurement  RGP Applicable		Shape factor	Applicable	Applicable	Not applicable
and axial measurement  Pupil & Cornea  Applicable  Not applicable  Not applicable		Zernike	Applicable	Applicable	Not applicable
measurementPupil & CorneaApplicableApplicableApplicableApplicableAxial measurementApplicableApplicableApplicableIOL calculationApplicableNot applicableNot applicableComparisonApplicableApplicableApplicable		RGP	Applicable	Applicable	Not applicable
IOL calculation Applicable Not applicable Not applicable Comparison Applicable Applicable Applicable		Pupil & Cornea	Applicable	Applicable	Applicable
Comparison Applicable Applicable Applicable		Axial measurement	Applicable	Applicable	Applicable
		IOL calculation	Applicable	Not applicable	Not applicable
Damont Applicable Applicable A 1, 11		Comparison	Applicable	Applicable	Applicable
Report 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:	WeiderZham
Printed Name:	Weida Zhan
Position/Title:	Management Representative
Contact Number:	13681849376