Shanghai MediWorks Precision Instruments Co., Ltd.
http://www.mediworks.com.cn
No.7, MingPu Phase II, No.3279 SanLu Road, MinHang District,201100, Shanghai, China
Phone: (86)-21-54260421 54260423 Fax: (86)-21-54260425

EU Declaration of Conformity

Manufacturer:

Shanghai MediWorks Precision Instruments Co., Ltd.
No.7, MingPu Phase II, No.3279 SanLu Road, MinHang District,201100, Shanghai, China
SRN number:CN-MF-000004251

whose single Authorized Representative:

CMC Medical Devices & Drugs SL
C/ Horacio Lengo
N18, Málaga, 29006, Spain

SRN number: ES-AR-000000293

We,the manufacturer,herewith declare under our sole responsibility that above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on medical (MDR).All supporting documentations are retained under the premises of the manufacturer.

Slit Lamp Microscopes

*(Model/Type:*S260,S260S,S280C,S260C,S290,S350C,S360,S360S,S390L,S390H*)*

meet the provisions of EU-REGULATION 2017/745 which apply to them.

Intended Use：Slit Lamp Microscopes are intended to observe the disease of the anterior structures and tissue damage of eyes.
The Basic UDI-DI of products are as follows:

069450875SlitLamp2P

Conformity Assessment Route:CHAPTER V SECTION 2 Art.52 (7) Regulation (EU)2017/745 on medical devices
The medical device has been assigned to RULE 10(Device class:class I) according to Annex VIII of the EU-REGULATION 2017/745. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex II of EU-REGULATION 2017/745.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: Shanghai MediWorks Precision Instruments Co., Ltd.
Address:No.7, MingPu Phase II, No.3279 SanLu Road, MinHang District, Shanghai, China

Shanghai, March 12. 2025

Place, date

Zhan Weida PRRC

Zhan Weida, Vice President/PRRC

Legally binding signature, Function

Digitally signed by Antonova Anna
Date: 2026.04.03 13:29:48 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

CERTIFICATE

Number: 6124989

The management system of:

Shanghai MediWorks Precision Instruments Co., Ltd.

No.7, MingPu Phase II, No.3279 SanLu Road, MinHang District
201100, Shanghai
China

including the implementation meets the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

Scope:
Design, Development, Manufacture, Distribution, and Servicing of Applanation Tonometers, Corneal Topographers, Vision Screeners, Three-dimensional Analysis Systems for the Anterior Eye Segment, Optical Biometers, Ophthalmic Surgical Microscopes, Automatic Fundus Cameras, Hand-held Fundus Cameras, Retina Lens, Slit Lamp Microscopes, Portable Slit Lamps, Vision Charts in the area of ophthalmic monitoring or diagnosis, Surgical Microscopes in the area of medical examination

Certificate expiry date: 1 March 2029
Certificate effective date: 1 March 2026
Certified since: 28 March 2023

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Certification Manager

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra.nl Company registration 09085396