

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Shanghai MediWorks Precision Instruments Co.,
Ltd.

Midwest Ophthalmic Services
Ballyloughane, Carrigkerry, Athea, Co.
Limerick, Ireland.
Tel: 069-76992

We, the manufacturer, herewith declare that the products

Slit Lamp Microscopes and accessories

(Model/Type: S390L, S390H,

S360DC, S350, S350S, S350C, S350DC, S280, S280S, S280CS360, S360S, S260, S260
S, SL2, SL400L, SL400H, SL300L, SL300H, SL350H, SL350L, SL450L, SL450H)

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

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: Zone A, 2nd Floor, No. 69, Lane 1985, Chunshen Road, Minhang District,
Shanghai, China

Shanghai, 12.12.2018

Place, date


Legally binding signature, function

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:

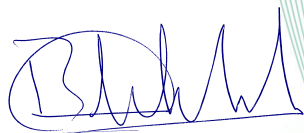
ISO 13485:2016 EN ISO 13485:2016

Scope:

Design, Development, Manufacture, Distribution, Installation and Servicing of Applanation Tonometers, Corneal Topographers, Vision Screeners, Three-dimensional Analysis Systems for the Anterior Eye Segment, Optical Biometers, 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

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

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M.A. McKenzie
Certification Manager

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