

EC Certificate

Production Quality Assurance Directive 93/42/EEC on Medical Devices. Annex V

Registration No.:

DD 2186731-1

Manufacturer:

Shanghai Mediworks Precision

Instruments Co., Ltd. No.7, MingPu Phase II,

No. 3279 SanLu Road, MinHang District,

201100 Shanghai

P.R. China

Products:

Applanation Tonometers, Ophthalmic Refractometer;

Aspects of manufacture concerned with conformity of products with the

metrological requirements of Slit lamp Biomicroscopes

Replaces Approval, Registration No.: DD 60147405 0001

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Page 1 of 1