



Declaration of Conformity



according to the Medical Devices Directive 93/42/EEC

Manufacturer: Shanghai MediWorks Precision Instruments Co.,Ltd.

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

Authorised representative: Midwest Ophthalmic Services

contact: Ballyloughane, Carrigkerry, Athea, Co. Limerick, Ireland.
Tel: 069-76992

We declare under our sole responsibility that

the Medical Device Product Name : Slit Lamp Microscopes and accessories

Type/model, batch/serial number, possibly sources and number of items (Where applicable) : S350,S350S,S350C,S280,S280S,S280C S360,S360S,S260,S260S,S390H, S390L

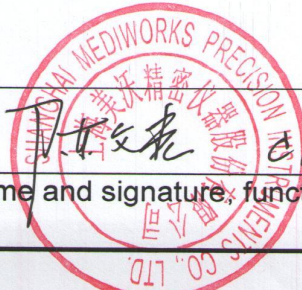
of class according to annex IX of directive : Class I
93/42/EEC

meets all the provisions of the directive 93/42/EEC which apply to it.

Applied harmonised standards, national standards or other normative documents	IEC 60601-1-2:2007/AC:2012	IEC 62304:2006+A1:2015
	IEC 60601-1:2005/AC:2012	IEC 62366:2007+A1:2014
	ISO 10939:2007	EN ISO 15223-1:2012
	EN ISO 10993.1:2009	ISO 15004-1:2006
	REACH Regulation 1907/2006	2011/65/UE

Conformity assessment procedure MDD 93/42/EEC Annex VII

Shanghai May 31, 2017
(place and date)


(name and signature, function)