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DECLARATION OF CONFORMITY

Manufacture's name: CHONGOING YEASN SCIENCE - TECHNOLOGY CO., LTD

Manufacture's address: 5 Danlong Road, Nan'an District, Chongqing, 400060, P.R.China
Deutsche Augenoptik AG

European Representative: Ziegeleistr. 18-24, 75417, Muehlacker, Germany

Identification of Device: Pupilometer

Model No.: HX-400

Classification (Annex VII) Class I

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacture. The supporting technical documentation is also retained at MailShop GmbH Augenoptik, Ziegeleistr. 18-24, 75417, Muehlacker, Germany.

DIRECTIVES



General application directive:

Medical Device Directive: 93/42/EEC concerning medical devices.

RoHS Directive: 2011/65/EU, WEEE Directive: 2012/19/EU

Standards

Applicable Standards to this product are:

EN ISO 15223-1:2012, EN 1041:2008, EN 14971:2012, EN ISO 15004-1:2009,
IEC 60601-1-2:2007, EN 60601-1-2:2007, IEC 60601-1:2012, EN ISO 10993-1:2010

Date CE mark was affixed: Apr 20th 2016

Place: Chongqing China

Effective Date: Apr. 20th. 2016

Signed by 
Zhou Yingying

Zhou Yingying

Sales Manager

Chongqing Yeasn Science & Technology Co., Ltd

Date of signature: Apr. 20th. 2016