NOTIFIED BODY No. 1023
Institute for Testing and Certification, Inc., Zlín, Czech Republic

EC CERTIFICATE

No. 08 0538 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class I with a measuring function:

Auto Ref/Keratometer

Models: CR-7000, CRK-7000

manufactured by company

ShangHai HUVITZ Co., Ltd
No. 188, Yuanguang Road, Baoshan, Shanghai, China

are manufactured under conditions fulfilling the quality system requirements of Annex V, Section 3.2, of the Directive 93/42/EEC.

The Notified Body No. 1023 has performed an audit of the above products manufacturing quality system, concerning aspects aimed to conformity of these products with the metrological requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex V, Sections 3.3, and 4, and Annex VII, Section 5, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803600424/2008, which is enclosed to this Certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **5th August 2018** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE marking followed by the number of the Notified Body according to this example:*

CE 1023

INSTITUTE FOR TESTING AND CERTIFICATION ITC 1023 NOTIFIED BODY

Issued in Zlín, on 6th August 2013

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

HUVITZ
SHANGHAI

EC Declaration of Conformity

We,

SHANGHAI HUVITZ Co., Ltd.

No.188, Yuanguang Road, Baoshang, Shanghia, China

with the authorized EC representative:

Lotus Global Co., Ltd.

47 Spenlow House Bermondsey London SE16 4SJ, UK

Tel: 0044-20-75868010

Fax: 0044-20-79006187

declare under sole responsibility that the

MEDICAL DEVICE

Product Name	: Auto Ref/Keratometer
Product Model number	: CR-7000, CRK-7000
Brand Name	: CHAROPS
Lot/Serial number	: start from 7CR8C1804, 7CK8G0110
Classification: Class	: I

Is in conformity with the essential requirements and provisions listed in the Annex I of the European Medical Devices Directive 93/42/EEC.

This Declaration of Conformity is based on EC Directive 93/42/EEC Annex VII, with reference to articles 1 and 3 of the directive.

Place and date of issue August 06, 2008

Name, Signature and position of manufacture CEO WOO HYUNG PARK

W. H. PARK