



Notified Body No. **0499**
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 08 0224 QS/NB/a

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 IIa,

COSMETIC COLOR SOFTCONTACT LENS

Models: Original

manufactured by company

Original medical CO.

#231-24, Dangjeong-Dong, Gunpo-Si, Gyeonggi-Do, 435-831, Korea

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

The Notified Body No. **0499** has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 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 Reports No. 803600466/2008 and 343600737/2010 that are 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 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 10th OTC 2016 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, 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 0499

Issued in Zlín, on 12th November 2008
Replaced by issue version a) on 22nd September 2010
(Replaces the withdrawn Certificate No. 08 0757 QS/NB issued on 12th November 2010)

RNDr. Radomír Čevelík
Representative of the Notified Body No. **0499**