№09281 №09281

ITC® №08625

Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

18 Nisan 2013

EC CERTIFICATE

No. 12 0886 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 IIb, models

Disposable Hot Biopsy Forceps and Disposable Snares and Reusable Hot Biopsy Forceps and Snares, Disposable Snare with bag and Reusable Snare with bag, Disposable Papillotome and Reusable Papillotome, Disposable Sphincterotomes and ERCP Cytology Brushes and ERCP Baskets and Reusable Sphincterotomes and ERCP Cytology Brushes and ERCP Baskets Disposable Forceps (Rotatable) and Reusable Forceps (Rotatable)

Alton (Shanghai) Medical Instruments Co., Ltd.

No. 693-jia, Lingshi Road 200072 Shanghai, P.R. China

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. 1023 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 Report No. 803601501/2012, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

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 30th October 2017 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 1023

Issued in Zlin, on 31st October 2012

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

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