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

EC CERTIFICATE

No. 12 0522 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 medical devices of Class IIa and IIb:

Electrosurgical Knife & Snare

Type: ClearCut Knife; Models: FM-EK0001, FM-EK0002, FM-EK0003, FM-EK0004, FM-EK0005
Type: ClearGrasp Snare; Models: FM-ES0001, FM-ES0002, FM-ES0003, FM-ES0004

Injection Catheter

Type: Clear-jet Injection Catheter; Models: FM-EI0001, FM-EI0002, FM-EI0003, FM-EI0004

Non-electric Biopsy Forceps

Type: Clear-Bite Biopsy Forceps; Models: FM-EF0001, FM-EF0002

manufactured by company

FINEMEDIX CO.,LTD.

B104 Venture Factory 1, 711 Hosan-dong, Dalseo-gu, Daegu 704-948, 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. 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 Reports No. 803601500/2012 and 803602121/2013, which are enclosed to this Certificate.

Conditions 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* ***28th June 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 Zlín, on 26th November 2013

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

Replaces the withdrawn EC Certificate No. 12 0522 QS/NB issued on 29th June 2012