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

EC CERTIFICATE

No. 09 0552 QS/NB/F

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 & IIb, models

Backbone Recovery System (Model: BRS-I),
Pedicle Screw Spinal Fixation System (Model: HC SPINAL SYSTEM)
Epidural Needle (Trade Name: HanChang Tuohy)
Epidural Catheter (Trade Name: CathFinder)
(For detailed specification refer to Annex; pages 1-2)

manufactured by company

Han Chang Co., Ltd.
#301-204 Bucheon Technopark, Samjeong-dong, Ojeong-gu, Bucheon-si, Gyeonggi-do 421-741, 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. 803601963/2013 which are 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 27th August 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

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

Issued in Zlin, on 15th october 2014
Replaced the withdrawn EC Certificate No. 09 0552 QS/NB/e issued on 30th September 2013