



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

EC CERTIFICATE

No. 13 0220 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

Non-Absorbable Sutures with/without needles

Types: Silk Braided (SK), Nylon Monofilament (NL),
Polyester Braided (PB), Polypropylene Monofilament (PM)

Suture needles sterile or non-sterile

manufactured by company

Heze Hope Medical Co., Limited.

No.1306 Zhonghua Road, 274012 Heze , Shandong, 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. 803600976/2013, 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 the above referenced models of the medical devices and it does not substitute the design or type-examination procedures.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **12th March 2018** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After receiving of the complementary EC Design-Examination Certificate related to the above referenced models, and fulfilling of 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 13th March 2013



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