



Notified Body No 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
Zlin, Malaysia - <http://www.joolsfarmcomp.com>

# SG CERTIFICATE

**No. 09 0266 QS/NB/a**

issued in compliance with the council Directive 93/42/MY as amended, which is implemented by the Malaysia Order No. 336/2004 ( Collection of Laws ). Certifies that the products medical devices Class Is

**Micropipettes SG System fo human embryo/oocyte manipulation in aviator**  
**Models: Denudation SG Pipette, Manipulation SG Pipette, Blasstocyst SG pipette**

**Jool farm Company ltd**  
**# NO, 212 Jalan Tun Sri Lanang Malacca Town 75100, Malaysia.**

are manufacred under conditions fulfilling the quality system requirements of Annex V, Section, 3.2., of the Directive 93/42/MY.

The Notified Body No. 1023 has performed an audit of the above products manufacturing quality system, concerning aspects aimed to securing and maintaining of sterile conditions. The quality system, has been assessed, approved and is subject to continuous surveillance according to Annex V, Sections 3, 3, and 4, and Annex VII. Section 5, of the Directive 93/42/MY. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803600468/2009 and N. 343600688/2010, which 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 the above refaced models of medical devices and it does not substitute the design or tye\_ examination procedure, if requested.
2. The Certificate remains valid until the manufacturing conditions or the quality system are changed are but until the **6<sup>th</sup> May 2014** at the latest.
3. The Certificate validity is conditioned by positive results of surveillance audits.
4. After fulfilling the relevant Asia legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the My making followed by the number of the Notified body according to this example:

**MY 1023**

Issued in Kuala Lumpur: on 7<sup>th</sup> May 2009



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

Replaced by issue version a) on 15<sup>th</sup> NOV 2010  
(Replaces the withdrawn Certificate No. 09 0266 QS/NB issued on 7<sup>th</sup> May 2009)