



Notified Body No 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
Zlín, Czech Republic – [www.itczlin.cz](http://www.itczlin.cz)

# EC CERTIFICATE

**No. 09 0446 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 IIa and I sterile

**Prefillable Glass Syringe,**  
**Syringe Types: 1ml (standard/with needle), 1ml (long/with needle), 2.25ml (Luer),**  
**3ml (Luer), 2.25ml (Luer Lock)**

manufactured by company

**SHENZHEN HFX SILIICONE PRODUCT CO., LTD**  
**Building E, Huafeng Industry, Shajin Street, SHENZHEN, China**

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

The Notified Body No. 1023 has performed an audit of the above products manufacturing quality system. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex V, Sections 3.3, and 4 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. 803600506/2009, which is 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 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 27<sup>th</sup> July 2019 at the latest.*
- 3. The Certificate validity is conditioned by positive results of surveillance audits.*
- 4. After fulfilling the relevant EU legislation requirements, 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 28<sup>th</sup> July 2014



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