



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

EC CERTIFICATE

No. 11 0110 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 Classes I sterile with measuring function and IIa, models

Sterile single Use Disposable Medical Devices (I.V. Set, Blood Transfusion Set, Hypodermic Syringes, Hypodermic Needles, Urine collection Bags)

manufactured by company

Agofa Lab

23, Sitaram Estate, Isanpur, Ahmedabad – 382 443, Gujarat, India.

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, 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/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601007/2011, 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 model 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 9th February 2016 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 model, the CE marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 10th February 2011



RNDr. Radomír Čevelík

Representative of the Notified Body No. 1023