



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

EC CERTIFICATE

No. 13 0131 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

Pressure Steam Sterilizer
Trade name: AM Model

Trade name: AM-PRE 12L, AM-PRE 18L, AM-PRE 22L,
AM-BAS 12L, AM-BAS 18L, AM-BAS 22L, AM-COM 8L

manufactured by company

Wenzhou Longde Medical Technology Co., Ltd.

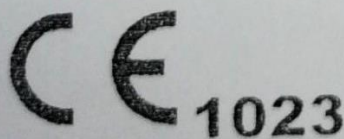
**A Building, No. 158 Gaoyi Road, Hi-Tech. Industrial Development Zone,
Wenzhou, China**

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. 803601554/2013 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 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 20th February 2018 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.*



Issued in Zlin, on 21st February 2013

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

CONFORM CU DOCUMENT
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Pressure Steam Sterilizer

Trade name: LF Model

Models: LF-22L, LF-18L, LF-17L, LF-16L, LF-12L, LF-8L, LF-22L-E, LF-18L-E, LF-17L-E, LF-16L-E, LF-12L-E, LF-8L-E, LF-22L-G, LF-18L-G, LF-17L-G, LF-16L-G, LF-12L-G, LF-8L-G

manufactured by company

Wenzhou Longde Medical Technology Co., Ltd.

**A Building, No. 158 Gaoyi Road, Hi-Tech. Industrial Development Zone,
Wenzhou, China**

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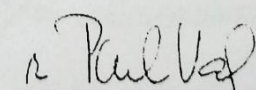
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