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

# EC CERTIFICATE

## No. 11 0703 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 medical devices of Class IIa:

**Mouth to Mouth Resuscitator, model: MTM 1001**
**Silicone Face Mask, models: MSK 1000, MSK 1001, MSK 1002, MSK 1003, MSK 1005**
**Oxygen Reservoir, models: ORV 1001, ORV 1002**
**Resuscitation Bag, models: RSB 1001, RSB 1002, RSB 1003, RSB 1004**
**Silicone Airways, models: ARW 1001, ARW 1002**
**Oxygen Hood, models: OHD 1001, OHD 1002**
**Foot suction, model: SUC 1001**
**Resuscitation Kit, models RSK 1001, RSK 1002, RSK 1003, RSK 1004**

manufactured by company

**Zeal Medical Pvt. Ltd.**
**4/19A, Piramal Industrial Estate, S.V. Road, Goregaon (W), Mumbai, Maharashtra, India.**

is 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. 803601195/2011, 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 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 **22nd August 2016** 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:*

CE 1023

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

Issued in Zlín, on 23rd August 2011

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