



Notified Body No 1023

INSTITUTE FOR TESTING AND CERTIFICATION, Inc.

Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 11 1081 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 product – medical device of Class IIb:

Neonatal Resuscitation Units

models: NRU1101A, NRU1101B, NRU1102A, NRU1102B, NRU2101A, NRU2101B, NRU2102A, NRU2102 B, NRU3001C, NRU3002C, NRU4001C, NRU4002C

manufactured by company

Zeal Medical Pvt. Ltd.

4/19-A, Piramal Industrial Estate, S.V. Road, Goregaon (W), Mumbai - 400062, Maharashtra, India

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

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. 803601227/2011, 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 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 18th December 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 models, the CE marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 19th December 2011




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