Products Certification Body
Institute for Testing and Certification, Inc., Zlin, Czech Republic
herein after refered to as "ITC"

TYPE - CERTIFICATE

No. 10 0078 T/ITC

confirms that the product – medical device of Class I according to Council Directive 93/42/EEC

Disposable ECG Electrodes, Chest Electrodes, Clamp Electrodes, TENS Electrodes, ESU Plates, ECG Gel, Ultrasound Gel

manufactured by company

YANCHENG TIANRUN ELECTRONIC INSTRUMENT FACTORY

Heqiao Industrial Area, West Qingnian Road, Yancheng City, Jiangsu Province, China

complies to the applicable essential requirements of the Directive 93/42/EEC.

Referring to intended use the ITC Products Certification Body has conducted with successful results the type-examination of the certified product according to the relevant parts of the above mentioned Directive and appropriate harmonized European standards. The detailed product description, documents, assessment procedures and evaluations of the examination are presented in the Final Report No. 313000026/2010

This Certificate is issued under the following conditions:

1. *It applies only to the above referenced models of the medical devices.*
2. *It does not imply that the ITC has performed any surveillance or control of its manufacture.*
3. *The manufacturer is obligated to assure that all medical devices of the respective models conform to the type approved by this Certificate.*
4. *The Certificate remains valid until the manufacturing conditions, the quality system or relevant legislation are changed but until the **28th February 2013** at the latest.*
5. *After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking according to this example:*

CE

Issued in Zlin, on 15th February 2010

Institut pro testování a certifikaci, a.s. Zlin

RNDr. Radomir Čevelík
General Director