



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

EC CERTIFICATE

No. 15 0426 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 54/2015 (Collection of Laws), certifies that the product – medical device of Class IIa

WIRELESS VITALS MONITOR

Brand Name: AMI Vitals+
Models: VA01, VA02, VA03, VA04
Brand Name: B.O.L.T
Models: VA01, VA02, VA03, VA04

manufactured by company

American Megatrends India Private Ltd.

Kumaran Nagar, Semmanchery Village, Chennai (TN), 600119, 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 product 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. 803602344/2015, 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 **27th August 2020** 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



R. Paul Ves
RNDr. Radomír Čevelík

Issued in Zlín, on 28th August 2015

Representative of the Notified Body No. 1023