

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHJECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

CE - CERTIFICATE

of full quality assurance system

No.: MED 070008

The Electrotechnical Testing Institute, Notified Body No. 1014, has decided that Quality System applied by

manufacturer

JABLOTRON ALARMS a.s.
Pod Skalkou 4567/33, 466 01 Jablonec nad Nisou, Czech Republic

for design, manufacture and final inspection of medical devices

Baby monitor NANNY model BM-01, BM-02 (class IIb)

complies with provisions of Annex 2 section 3 of Governmental Order No. 336/2004 Coll. (Annex II section 3 of the Council Directive 93/42/EEC) incl. amendments.

This decision is based on the results presented in report No. 104491-02 of: 29.11.2011

In accordance with Art. 5 of Governmental Order No. 336/2004 Coll. (Art. 17 of Directive 93/42/EEC), incl. amendments the above specified medical device must be labelled CE 1014.

The certified manufacturer is subject to a surveillance audit by the notified body in accordance with section 5 of Annex 2 of Governmental Order No. 336/2004 Coll. (Annex II section 5 of Directive 93/42/EEC) incl. amendments, and validity of the Certificate is subject to regular supervision. The manufacturer must inform the notified body about any intention resulting in significant modification of quality system or scope of included medical products. In the event that the conditions under which the Certificate has been issued are violated, the notified body may suspend the Certificate's validity or cancel the Certificate.

Edition 2

Date of first issue of Certificate 6.3.2009 with validity until 31.1.2012

The validity of current Certificate is limited until: 1.2.2017

1.2.2012

Prague

Miroslav Sedláček
Certification and Inspection Manager



Stamp



104491-02

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Pod Lisem 129, 171 02 Praha 8 - Troja

CERTIFICATE

No.: 1130105

Product: Baby Respiration Monitor

Type: BM-02

Rating: Baterie 2x 1,5 V AA; 0.2 mA/100 mA

Ordering firm: JABLOTRON ALARMS a.s.
Pod Skalkou 4567/33, 466 01 Jablonec nad Nisou, Czech Republic

Manufacturer: JABLOTRON ALARMS a.s.
Pod Skalkou 4567/33, 466 01 Jablonec nad Nisou, Czech Republic

Trade mark:

The test results are stated in the test-report No.: 001109-01/01 of: 19.04.2010

A sample of the product was found to be in conformity with:
ČSN EN 60601-1 ed.2:2007

The validity of the certificate is limited to: 29.2.2016

25.2.2013

Prague

Jarmil Mikulík
Deputy Head of Certification Body



Stamp



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