JABLOTRON
CREATING ALARMS

EU DECLARATION OF CONFORMITY (DoC)

The manufacturer

Name:	JABLOTRON ALARMS a.s.
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declares that the declaration of conformity is issued under our sole responsibility and belongs to the following product(s):

Type designation:	BM-02
In configuration with:	
Trade name:	Baby breathing monitor
Intended use:	The BM-02 is the medical device risk class **IIb** intended to monitoring baby's breathing

is in a compliance with the relevant Union harmonisation legislation:

the directives 93/42/EC and 2007/47/EC (MED) of the European Parliament and of the Council essential requirements conccerning medical devices and the directive 2011/65/EU (ROHS) of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment

The following harmonized standards and technical specifications have been applied:

EN 60601-1:2006, EN 60601-1-2:2007, EN 60601-1-6:2010, EN 60601-1-11:2010, EN ISO 10993-1:2009, EN 62366:2008, EN ISO 14155:2010, EN ISO 14971:2012, EN ISO 13485:2012, EN 50581:2012

and other standards:

EN ISO 15223-1:2012

Conformity assessment approved by EU Notified Body No. 1014 EZU Praha accordinng to Council Directive 93/42/EC, 2007/47/EC, Annex II.

This EU declaration of conformity is issued on exclusive manufacturer responsibility and is valid for batch codes starting No. 1603250005 (control unit).

The product is safe when is used for its intended purpose and according to producer manual.

In Jablonec nad Nisou 20/04/2016

David Beneš
executive director

CE 1014