

EU DECLARATION OF CONFORMITY (DoC)

EN

The manufacturer

Name: JABLOTRON ALARMS a.s.
Street, Postcode, Town: Pod Skalkou 4567/33, 466 01, Jablonec nad Nisou
Country: Czech Republic
Entrepreneurial permit number: CZ28668715
Tel./Fax: +420 483 559 811 / +420 483 313 183
WWW / E-mail: www.jablotron.com / export@jablotron.cz

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 product is a medical device of risk class IIb and is 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 concerning 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 + A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010 + A1:2015, EN 60601-1-11:2015,
EN ISO 10993-1:2009, EN 62366:2008 + A1:2015, EN ISO 14155:2011, EN ISO 14971:2012,
EN ISO 13485:2016, EN 50581:2012

This EU declaration of conformity is issued on exclusive manufacturer responsibility and is valid for batch codes starting No. **1809300005** (control unit).

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

In Jablonec nad Nisou 2019/06/28

Miroslav Jarolím
executive director

