

**EU DECLARATION OF CONFORMITY (DoC)**

EN

**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-03  
**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 compliance with the relevant Union harmonization legislation:**

The directive 93/42/EC and 2007/47/EC (MED) of the European Parliament and of the council essential requirement concerning medical devices and the directive 2011/65/EU (RoHS) of the European Parliament and of the council on the restrictions of the use of certain hazardous substances in electrical and electronic devices.

**The following harmonized standards and technical specifications have been applied:**

EN 60601-1:2006 +A1:2013, 60601-1-2:2015, EN 60601-1-6:2010,  
EN 60601-1-11:2015, EN ISO 10993-1:2009, EN 62366-1:2015 +A1:2015, EN ISO 14155:2011,  
EN ISO 14971:2019, EN ISO 13485:2016, EN 50581:2013

This EU declaration of conformity is issued on exclusive manufacturer responsibility and is valid for batch codes starting from No. 8595614125949 (control unit).

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

In Jablonec nad Nisou 01.09.2020

Miroslav Jarolím  
Executive director

