JABLOTRON

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

Manufacturer name	**JABLOTRON ALARMS a.s.**
Manufacturer address and contact details	Pod Skalkou 4567/33, 46601, Jablonec nad Nisou, Czech Republic, support@jablotron.cz
Single Registration Number (SRN)	CZ-MF-000033469

We, as the manufacturer declare under our sole responsibility:

- for the listed **Directive Certificates** in the attached schedule the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificates** as listed in the attached schedule

- Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterward.
- Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR is in place.

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- **Devices as listed in the attached schedule**
  - The devices continue to comply with the AIMDD or MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

JABLOTRON ALARMS a.s.
Pod Skalkou 4567/33, 46601, Jablonec nad Nisou, Czech Republic

Ing. Václav Kraus, Ph.D., Member of Board

Dated: 10.4.2024

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
Baby Breathing Monitor, BM-02 **(Monitor dechu miminka, BM-02)**	MED 210003	26.5.2024	Electrotechnical Testing Institute – Czech Republic, NB 1014	Institute for Testing and Certification, NB 1023	31.12.2028	N/A
BM-03 Baby Breathing Monitor **(BM-03 Monitor dechu miminka)**	MED 200025	26.5.2024	Electrotechnical Testing Institute – Czech Republic, NB 1014	Institute for Testing and Certification, NB 1023	31.12.2028	N/A

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