650-439-1596

Fax: 650-618-2799

alivecor.com

189 N Bernardo Avenue, Suite 100
Mountain View, CA 94043

MANUFACTURER SELF-DECLARATION ON THE APPLICABILITY OF ART.120 (2) AND (3) OF REGULATION (EU) 2017/745

We, AliveCor, Inc. established in 189 N Bernardo Ave, Suite 100, Mountain View, CA 94043, USA hereby declare that the EC Certificate mentioned in the table below (hereinafter "the Certificate") satisfies the conditions mentioned in Art.120 paragraph 2 and 3 of Regulation (EU) 2017/745.

In particular, we hereby confirm that:

1.The Certificate was issued after 25 May 2017, it was valid on May 26, 2021 and it was not suspended or withdrawn at the moment of its expiry.

2. The Certificate expired before March 20, 2023 and before the Certificate's expiry, AliveCor, Inc. signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to Regulation (EU) 2017/745 for the conformity assessment in respect of the devices covered by the Certificate or in respect of the devices intended to substitute those devices. **The Agreement was signed with the with the Notified Body GMED SAS No. 0459 on 06/07/2022.**

3. The devices covered by the Certificate continue to comply with Directive 93/42/EEC.

4. There are no significant changes in the design and intended purpose of the device(s) covered by the Certificate.

5.The requirements of Regulation (EU) 2017/745 relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are applied apply to devices covered by the Certificate in place of the corresponding requirements in Directive 93/42/EEC.

6. The devices covered by the Certificate do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

7. No later than 26 May 2024, AliveCor, Inc. will put in place a quality management system in accordance with Article 10(9) of Regulation (EU) 2017/745.

Signed by: Dated: 26th April, 2023

Shilpy Upadhyay,
Senior International Regulatory Affairs Manager
AliveCor, Inc.