STATEMENT

Digitally signed by Şarco Alexandru
Date: 2024.10.04 10:55:06 EEST
Reason: MoldSign Signature
Location: Moldova

To Whom It May Concern,

VivaChek Biotech (Hangzhou) Co., Ltd, with registered address at: Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China, states that:

The listed devices are 'legacy products' whose conformity assessment procedure was carried out before May 26, 2022 in accordance with IVDD 98/79/EC. The self-declaration is according to Annex III (excluding Section 6) of the Directive. According to article 110 of the Regulation (EU) 2017/746, "legacy devices" mentioned below, under Article 110 of Regulation (EU) 2017/746, as amended 2024/0021(COD):

3a. Devices which have a certificate that was issued in accordance with Directive 98/79/EC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until 31 December 2028.

3b. Devices for which the conformity assessment procedure pursuant to Directive 98/79/EC did not require the involvement of a notified body, for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with that Directive, and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until the following dates:
(a) 31 December 2027, for class D devices;
(b) 31 December 2028, for class C devices;
(c) 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition.

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:
(a) those devices continue to comply with Directive 98/79/EC;
(b) there are no significant changes in the design and intended purpose;

VivaChek Biotech (Hangzhou) Co., Ltd
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(c) the devices 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;
(d) no later than 26 May 2025, the manufacturer has put in place a quality management system in accordance with Article 10(8);

This declaration concerns in vitro diagnostic medical devices included in Annex I.

Sincerely,

Place and date of issue of the declaration:	**Name, Function, and Signature**
2024/09/03	

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Annex 1

List of in vitro diagnostic medical devices placed on the market after 26 May 2022 pursuant to Article 110 of Regulation (EU) 2017/746

Model	**Product Description**	**Classification under IVDR**
VGM49	VivaChek Ino X Blood Glucose Monitoring System	Class C
VGM49	VivaChek Ino X Blood Glucose Meter	Class C
VGS01	VivaChek Ino Blood Glucose Test Strips	Class C
VGC01	VivaChek Ino Control Solution	Class C

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