



Polish Centre for Testing and Certification

BM.433.0130.2021.1129.22.JJ

Warsaw, 05.07.2022

**Xiamen Wiz Biotech Co., Ltd.,
3-4 Floor, NO.16 Building, Bio-medical Workshop,
2030 Wengjiao Xi Road, Haicang District, Xiamen City,
Fujian Province, 361026, P.R. China**

Pursuant the application for change dated 05.07.2022 Polish Centre for Testing and Certification kindly inform that the review of changes to the Xiamen Wiz Biotech Co., Ltd., product has been accomplished. Provided documents indicate this change is acceptable and there is no adverse impact to the assays and their performance.

On the basis of the documents provided, the change in the shelf life from 12 months to 24 months is accepted. Please remember that results of further real-time stability studies should be provided to PCBC on an ongoing basis.

Also the notified change regarding the change of the symbols on the packaging to the word description and the removal of symbols from the IFU is accepted.

Implementation of the change does not represent a significant change in design or intended purpose under IVDR 2017/746 Article 110(3) and the related certificate no. 1434-IVDD-043/2022 issued 15.03.2022 remains valid until 27.05.2025.

Yours Sincerely,

Manager In Vitro Diagnostic Medical
Device Certification Division

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