EU DECLARATION OF CONFORMITY

According to of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Name and address of the manufacturer:	BioTeke Corporation (Wuxi) Co., Ltd No. 90, Huiming Road, Huishan, Wuxi City, Jiangsu, 214000, China
SRN:	CN-MF-000007517
Trademark:	BioTeke
Name and address European Representative:	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
Trade name:	Saliva Pregnancy Test Kit
Product name:	Saliva Pregnancy Test Kit
Reference number	ICA2235
Intended use	The Saliva Pregnancy Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in saliva to aid in the early detection of pregnancy.
Basic UDI-DI:	697454156019LE
Classification:	Class B, rule 4a
Conformity assessment route:	IVDR Annex IX
EU Technical Documentation Assessment Certificate No.:	EU-TDA-FI-43117-800031-2025
EU Quality Management System Certificate No.:	EU-QMS-FI-40845-800031-2025
Name, address and ID of the Notified Body:	Sertio Oy Biokatu 10, 33520 Tampere, Finland CE 3018

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on on in vitro diagnostic medical devices. All supporting documentations are retained under the premises of the manufacturer.

BIOTEKE CORPORATION (WUXI) CO., LTD 无锡 百泰克生物技术 有限公司 91320206193280 6

Date: 2026-07-10

Signature: Zhou Zhitu

Place: Wuxi, Jiangsu, China

Name and position: Zhou Zhitu General manager