

EU DECLARATION OF CONFORMITY

Manufacturer name and address:

ZINEXTS LIFE SCIENCE CORP.

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SRN (Single Registration Number):

TW-MF-000026758

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We, **ZINEXTS LIFE SCIENCE CORP.** hereby declare under our sole responsibility that the devices listed in the attached Annex comply with the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices.

This Declaration is applicable to the devices listed in the Annex to the Declaration of Conformity. Risk class and classification rules according to Annex VIII of REGULATION (EU) 2017/746 and other relevant data, e.g., intended purpose, catalogue number are provided in the Annex to the Declaration of Conformity.

The conformity assessment procedure is applied according to IVDR Art 48. The conformity assessment has been performed according to Annex I and Annex II & III (Class A).

The following Standards have been used and in relation to which conformity is declared:

ISO 13485:2016

ISO 14971:2019



Manufacturer's PRRC: Theresa Lin

Position: Regulatory Manager

Signature:

A handwritten signature in blue ink that reads "Theresa Lin".

Issue Place: New Taipei City

Issue Date: 22/10/2024

Company Stamp:





Annex - List of Devices Covered by the Declaration of Conformity

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Short description and Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	EMDN/GMDN code
1	BioMagPure 12 Plus	BS-060202	Instrument and accessories for automated extraction and purification of nucleic acid from various biological samples	Class A	Annex VIII, Rule 5b	471988968ZP01005YD	W02069099/ 60736
2	BioMagPure Blood DNA Extraction kit 200	BS-060201-AK	Reagents and consumables for extracting genomic DNA from biological sample	Class A	Annex VIII, Rule 5a	471988968ZP02001YC	W02069085/ 52521
3	BioMagPure Blood DNA Extraction kit 1200	BS-060201-BK	Reagents and consumables for extracting genomic DNA from biological sample	Class A	Annex VIII, Rule 5a	471988968ZP02002YE	W02069085/ 52521
4	BioMagPure Viral Nucleic Acid Extraction kit	BS-060201-CK	Reagents and consumables for extracting viral nucleic acid from biological samples	Class A	Annex VIII, Rule 5a	471988968ZP02003YG	W02069085/ 52521
5	BioMagPure Tissue DNA Extraction kit	BS-060201-DK	Reagents and consumables for extracting genomic DNA from biological samples	Class A	Annex VIII, Rule 5a	471988968ZP02004YJ	W02069085/ 52521
6	BioMagPure Cultured Cell DNA Extraction kit	BS-060201-EK	Reagents and consumables for extracting genomic DNA from cultured cells	Class A	Annex VIII, Rule 5a	471988968ZP02005YL	W02069085/ 52521



7	BioMagPure Bacterial DNA Extraction kit	BS-060201-FK	Reagents and consumables for extracting bacterial DNA from biological samples	Class A	Annex VIII, Rule 5a	471988968ZP02006YN	W02069085/ 52521
8	BioMagPure HPV DNA Extraction Kit for Swab Samples	BS-060201-GK	Reagents and consumables for extracting HPV DNA from swab samples	Class A	Annex VIII, Rule 5a	471988968ZP02007YQ	W02069085/ 52521
9	BioMagPure TB DNA Extraction Kit	BS-060201-IK	Reagents and consumables for extracting Mycobacterium tuberculosis DNA from biological samples	Class A	Annex VIII, Rule 5a	471988968ZP02008YS	W02069085/ 52521
10	BioMagPure FFPE DNA Extraction Kit	BS-060201-JK	Reagents and consumables for extracting genomic DNA from formalin-fixed, paraffin-embedded (FFPE) samples and needle biopsies	Class A	Annex VIII, Rule 5a	471988968ZP02009YU	W02069085/ 52521
11	BioMagPure Forensic DNA Extraction Kit	BS-060201-KK	Reagents and consumables for extracting genomic DNA from a wide range of forensic & human identity samples	Class A	Annex VIII, Rule 5a	471988968ZP02010YD	W02069085/ 52521
12	BioMagPure Viral/Pathogen Nucleic Acids Extraction Kit A	BS-060201-LK	Reagents and consumables for extracting viral DNA/RNA and pathogen DNA from cell-free samples	Class A	Annex VIII, Rule 5a	471988968ZP02011YF	W02069085/ 52521
13	BioMagPure Viral/Pathogen Nucleic Acids Extraction Kit B	BS-060201-MK	Reagents and consumables for extracting viral DNA/RNA and pathogen DNA from cell-rich samples	Class A	Annex VIII, Rule 5a	471988968ZP02012YH	W02069085/ 52521
14	BioMagPure Viral RNA Extraction Kit	BS-060201-NK	Reagents and consumables for extracting viral RNA from biological samples	Class A	Annex VIII, Rule 5a	471988968ZP02013YK	W02069085/ 52521
15	BioMagPure Total RNA Extraction Kit	BS-060201-PK	Reagents and consumables for extracting total RNA from a variety of sample types	Class A	Annex VIII, Rule 5a	471988968ZP02015YP	W02069085/ 52521



16	BioMagPure Viral Nucleic Acid Extraction Kit LV	BS-060201-QK	Reagents and consumables for extracting viral nucleic acid from large volume biological samples	Class A	Annex VIII, Rule 5a	471988968ZP02016YR	W02069085/ 52521
17	BioMagPure CFC DNA Extraction Kit	BS-060201-RK	Reagents and consumables for extracting circulating DNA from biological samples	Class A	Annex VIII, Rule 5a	471988968ZP02017YT	W02069085/ 52521