

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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SRN (Single Registration Number):

BE-AR-000000106

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).

Manufacturer's PRRC: Theresa Lin

Position: Regulatory Manager

Signature:



Issue Place: New Taipei City

Issue Date: 23/08/2022

Stamp:



Attachments – DoC IVDR Zinexts – V1.1 – 23/08/2022

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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 | GMDN code |
|---|--|--------------------------------|--|---------|-----------------------------|--------------------|-----------|
| 1 | MagPurix 12 EVO Automated Nucleic Acid Purification System | ZP01018 | Instrument and accessories for automated extraction and purification of nucleic acid from various biological samples | Class A | Annex VIII, Rule 5b | 471988968ZP01018YN | 60736 |
| 2 | MagPurix 24 EVO Automated Nucleic Acid Purification System | ZP01019 | Instrument and accessories for automated extraction and purification of nucleic acid from various biological samples | Class A | Annex VIII, Rule 5b | 471988968ZP01019YQ | 60736 |
| 3 | MagPurix 12A Automated Nucleic Acid Purification System | ZP01005 | Instrument and accessories for automated extraction and purification of nucleic acid from various biological samples | Class A | Annex VIII, Rule 5b | 471988968ZP01005YD | 60736 |
| 4 | MagPurix 24 Automated Nucleic Acid Purification System | ZP01003 | Instrument and accessories for automated extraction and purification of nucleic acid from various biological samples | Class A | Annex VIII, Rule 5b | 471988968ZP01003Y9 | 60736 |

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| 5 | MagPurix 12S Automated Nucleic Acid Purification System | ZP01001 | Instrument and accessories for automated extraction and purification of nucleic acid from various biological samples | Class A | Annex VIII, Rule 5b | 471988968ZP01001Y5 | 60736 |
| 7 | ZiXpress 32Dx Automated Nucleic Acid Purification System | ZP01021 | Instrument and accessories for automated extraction and purification of nucleic acid from various biological samples | Class A | Annex VIII, Rule 5b | 471988968ZP01021YB | 60736 |
| 8 | ZiXpress 64Dx Automated Nucleic Acid Purification System | ZP01022 | Instrument and accessories for automated extraction and purification of nucleic acid from various biological samples | Class A | Annex VIII, Rule 5b | 471988968ZP01022YD | 60736 |
| 9 | ZiXpress 96Dx Automated Nucleic Acid Purification System | ZP01023 | Instrument and accessories for automated extraction and purification of nucleic acid from various biological samples | Class A | Annex VIII, Rule 5b | 471988968ZP01023YF | 60736 |
| 10 | MagPurix Blood DNA Extraction Kit 200 | ZP02001 | Reagents and consumables for extracting genomic DNA from biological sample | Class A | Annex VIII, Rule 5a | 471988968ZP02001YC | 52521 |
| 11 | MagPurix Blood DNA Extraction Kit 1200 | ZP02002 | Reagents and consumables for extracting genomic DNA from biological sample | Class A | Annex VIII, Rule 5a | 471988968ZP02002YE | 52521 |
| 12 | MagPurix Viral Nucleic Acid Extraction Kit | ZP02003 | Reagents and consumables for extracting viral nucleic acid from biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02003YG | 52521 |

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| 13 | MagPurix Tissue DNA Extraction Kit | ZP02004 | Reagents and consumables for extracting genomic DNA from biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02004YJ | 52521 |
| 14 | MagPurix Cultured Cell DNA Extraction Kit | ZP02005 | Reagents and consumables for extracting genomic DNA from cultured cells | Class A | Annex VIII, Rule 5a | 471988968ZP02005YL | 52521 |
| 15 | MagPurix Bacterial DNA Extraction Kit | ZP02006 | Reagents and consumables for extracting bacterial DNA from biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02006YN | 52521 |
| 16 | MagPurix HPV DNA Extraction Kit for Swab Samples | ZP02007 | Reagents and consumables for extracting HPV DNA from swab samples | Class A | Annex VIII, Rule 5a | 471988968ZP02007YQ | 52521 |
| 17 | MagPurix TB DNA Extraction Kit | ZP02008 | Reagents and consumables for extracting Mycobacterium tuberculosis DNA from biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02008YS | 52521 |
| 18 | MagPurix FFPE DNA Extraction Kit | ZP02009 | Reagents and consumables for extracting genomic DNA from formalin-fixed, paraffin-embedded (FFPE) samples and needle biopsies | Class A | Annex VIII, Rule 5a | 471988968ZP02009YU | 52521 |
| 19 | MagPurix Forensic DNA Extraction Kit | ZP02010 | Reagents and consumables for extracting genomic DNA from a wide range of forensic & human identity samples | Class A | Annex VIII, Rule 5a | 471988968ZP02010YD | 52521 |
| 20 | MagPurix Viral/Pathogen | ZP02011 | Reagents and consumables for extracting viral DNA/RNA and pathogen DNA from cell-free samples | Class A | Annex VIII, Rule 5a | 471988968ZP02011YF | 52521 |

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| | Nucleic Acids Extraction Kit A | | | | | | |
| 21 | MagPurix Viral/Pathogen Nucleic Acids Extraction Kit B | ZP02012 | Reagents and consumables for extracting viral DNA/RNA and pathogen DNA from cell-rich samples | Class A | Annex VIII, Rule 5a | 471988968ZP02012YH | 52521 |
| 22 | MagPurix Viral RNA Extraction Kit | ZP02013 | Reagents and consumables for extracting viral RNA from biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02013YK | 52521 |
| 23 | MagPurix Total RNA Extraction Kit | ZP02015 | Reagents and consumables for extracting total RNA from a variety of sample types | Class A | Annex VIII, Rule 5a | 471988968ZP02015YP | 52521 |
| 24 | MagPurix Viral Nucleic Acid Extraction Kit LV | ZP02016 | Reagents and consumables for extracting viral nucleic acid from large volume biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02016YR | 52521 |
| 25 | MagPurix CFC DNA Extraction Kit | ZP02017 | Reagents and consumables for extracting circulating DNA from biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02017YT | 52521 |
| 26 | MagPurix cfDNA Extraction Kit Plus | ZP02024 | Reagents and consumables for extracting circulating DNA from biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02024YQ | 52521 |
| 27 | MagPurix cfDNA Extraction Kit LV | ZP02025 | Reagents and consumables for extracting circulating DNA from large volume biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02025YS | 52521 |

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| 28 | MagPurix Coronavirus RNA Extraction Kit | ZP02027 | Reagents and consumables for extracting viral RNA from a variety of sample types | Class A | Annex VIII, Rule 5a | 471988968ZP02027YW | 52521 |
| 29 | ZiXpress Viral DNA/RNA Extraction Kit | ZP02201 | Reagents and consumables for extracting viral nucleic acid from diverse biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02201YN | 52521 |
| 30 | ZiXpress Bacteria Genomic DNA Extraction Kit | ZP02202 | Reagents and consumables for extracting bacteria DNA from biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02202YQ | 52521 |
| 31 | ZiXpress Whole Blood Genomic DNA Extraction Kit | ZP02203 | Reagents and consumables for extracting genomic DNA from whole blood and other biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02203YS | 52521 |
| 32 | ZiXpress Tissue Genomic DNA Extraction Kit | ZP02204 | Reagents and consumables for extracting genomic DNA from tissue and other biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02204YU | 52521 |
| 33 | ZiXpress Viral RNA Extraction Kit | ZP02205 | Reagents and consumables for extracting viral RNA from diverse biological samples | Class A | Annex VIII, Rule 5a | 471988968ZP02205YW | 52521 |
| 34 | 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 | 60736 |
| 35 | 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 | 52521 |

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|----|--|--------------|---|---------|---------------------|--------------------|-------|
| 36 | 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 | 52521 |
| 37 | 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 | 52521 |
| 38 | 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 | 52521 |
| 39 | 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 | 52521 |
| 40 | 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 | 52521 |
| 41 | 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 | 52521 |
| 42 | 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 | 52521 |
| 43 | 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 | 52521 |

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|----|--|--------------|--|---------|---------------------|--------------------|-------|
| 44 | 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 | 52521 |
| 45 | 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 | 52521 |
| 46 | 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 | 52521 |
| 47 | 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 | 52521 |
| 48 | 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 | 52521 |
| 49 | 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 | 52521 |
| 50 | 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 | 52521 |