



DECLARATION OF CONFORMITY

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

Manufacturer: Lansion Biotechnology Co.,Ltd.

Eudamed Actor ID: CN-MF-000001086

Address: No.6, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, P.R. China

Authorized representative: Lotus NL B.V.

Eudamed Actor ID: NL-AR-000000121

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

NAME	REF	Basic UDI-DI
Incubator	F1-10	69717632236785001UT
	F3-30	69717632236785002UV
LA-100 Handheld Coagulation Analyzer	E1-100	69717632262542001RM
LS-1100 Dry Fluorescence Immunoassay Analyzer	L5-1100	69717632247057001SH
LS-2100 Dry Fluorescence Immunoassay Analyzer	L6-2100	69717632247057002SK
LS-4000 Dry Fluorescence Immunoassay Analyzer	L4-4000	69717632248014001QZ

Risk Class: Class A (In accordance with the rule set out in Annex VIII of Regulation (EU) 2017/746)

Conformity assessment route: Declaration of Conformity IVDR Annex VIII, Rule 5.

Applicable Standards: Attachment I

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.

We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Name of authorized signatory: Bingbing Zhao

Position held in the company:

Manager of Quality Department

Date: Dec. 13th, 2023

Seal/Stamp:

Lansion Biotechnology Co.,Ltd.

Place: Nanjing, China

Attachment I

References to other union legislations, standards and common specification (if applicable) applied:

- 1) EN ISO13485:2016 Medical devices - Quality management systems- Requirements for regulatory purposes
- 2) EN ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- 3) EN ISO 14971:2019 Medical devices - Application of risk management to medical devices
- 4) ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 5) ISTA-2A:2011: Series Partial Simulation Performance Test Procedure (Packaged - Products 150lb (68kg) or less)
- 6) ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer Information supplied by the manufacturer with medical devices
- 7) IEC 62366-1:2015+A1:2020 Medical Device Part 1 Application of usability engineering to medical devices
- 8) EN ISO 18113-1:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements
- 9) EN 592-2002 Instructions for use for in vitro diagnostic instruments for self-testing
- 10) EN ISO 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- 11) EN ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good clinical practice
- 12) MEDDEV 2.7.1 Rev.4 GUIDELINES ON MEDICAL DEVICES
- 13) EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline Second Edition
- 14) IEC 61010-1:2010+A1:2016 Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
- 15) IEC 61010-2-101:2019 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use-Part 2-101: Particular Requirements for in Vitro Diagnostic (IVD) Medical

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Equipment

- 16) IEC 61326-1:2012 Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements
- 17) IEC 61326-2-6:2012 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- 18) ASTM D4169 DC13 Standard Practice for Performance Testing of Shipping Containers and Systems

必有限公司