Declaration of Conformity

Manufacturer:
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SRN: AL-AR-000000444

Basic UDI-DI: Refer to Appendix.
Product Name: Refer to Appendix.
Intended Purpose: Refer to Appendix.
Package Size: Refer to Appendix.

(EC) Certificate(s): Not applicable.
Classification: Refer to Appendix.
Conformity assessment procedure: Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX

We herewith declare that the above-mentioned products meet the Regulation (EU) 2017/746 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and the transposition into national law. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.

General Applicable Regulation:
REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017.

Standards Applied of IVD Reagent

EN ISO 13485:2016	EN 13612: 2002	EN ISO 18113-1: 2024
EN ISO 14971:2019	EN ISO 15223-1: 2021	EN ISO 18113-2: 2024
ISO 780:2015	EN ISO 17511: 2021	ISO 20916:2019
EN ISO 23640: 2015	EN 13641:2002	ISO/TR 20416: 2020
IEC 62366-1:2015		

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Date: 2025.12.30 09:49:09 EET
Reason: MoldSign Signature
Location: Moldova
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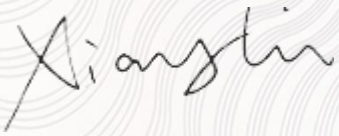
Standards Applied of IVD Analyzer

EN ISO 13485:2016	EN 61010-1:2010 + A1:2019	EN ISO 18113-1: 2024
EN ISO 14971:2019	EN ISO 15223-1: 2021	EN ISO 18113-2: 2024
EN 62304: 2006 + A1:2015	EN IEC 61010-2-081: 2019	EN IEC 61010-2-101: 2017
EN IEC 62366-1:2015 + A1:2020	EN IEC 61326-1:2021	EN 61326-2-6:2021

Signature: 

CE

Name : Xiang Lei

Position: Director

Place, Date of Issue: Shenzhen, 2025-04-14

Appendix I

No.	Product Name	Specification	REF No.	Basic UDI DI	Intended Purpose	Classification
1	Automated ECL Immunoassay Analyzer	eCL8000, eCL8000i, eCL8000p,eCL8000x	/	6970341680120502H9	This product employs the tris (2,2'-bipyridine) ruthenium(II)-based direct ECL method, and is used in conjunction with matched test reagents; it is clinically intended for qualitative or quantitative testing of analytes in human samples.	Annex VIII, Class A, Rule 5
2	Automated ECL Immunoassay Analyzer	eCL9000, eCL9600, eCL9900, eCL9900i	/	6970341680120503HB	With the direct electrochemical luminescence method based on tris(2,2′-bipyridyl)ruthenium, the instrument is clinically used together with the matching test reagents for the qualitative or quantitative tests of analytes in human serum and plasma samples.	Annex VIII, Class A, Rule 5
3	Automated ECL Immunoassay Analyzer	eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p	/	6970341680120504HD	This product utilizes the tris (2,2'-bipyridine) ruthenium (II) - based direct ECL method. It is designed for use with matching test reagents to qualitatively or quantitatively detect analytes in serum, plasma, or other human body samples for clinical analysis.	Annex VIII, Class A, Rule 5
4	Assay Cup	300T, 3000T	679011 679012	6970341680320506 3JK	It is used in combination with Lifotronic automatic chemiluminescence immunoassay to store and incubate the reaction solution and complete the incubation process of immune reaction.	Annex VIII, Class A, Rule 5
5	Auffer	480 mL 6×480 mL 2×1 L 4×1 L 2×2 L 4×2 L	679005 679004 0320501804 0320501805 0320501801 0320501806	6970341680320506 4JM	Auffer is used to clean the fluid system and measurement cell in the course of assay. Auffer can be used with all reagent lots.	Annex VIII, Class A, Rule 5
6	Buffer	480 mL 6×480 mL 2×1 L 4×1 L 2×2 L 4×2 L	679007 679006 0320501904 0320501905 0320501901 0320501906	6970341680320506 5JP	Buffer is used to provide and maintain electrochemical reaction environment in ECL Immunoassay Analyzers. The major functions of Buffer present as follows: ● Forming a stable surface structure on the electrode ● Transporting the reaction mixture ● Cleaning magnetic particles enveloped with immuno-complexes ● Generation electrochemilumescent signal. Buffer can be used with all reagent lots.	Annex VIII, Class A, Rule 5
7	Concentrated	1 L,	679009	6970341680320506 6JR	Concentrated washing buffer is used to clean pipette line after liquid transfer in eCL series	Annex VIII,

	Washing Buffer	6×1 L	679008		analyzer.	Class A, Rule 5
8	Enhanced Washing Buffer	50 mL, 2×50 mL	679017 0320507402	69703416803205067JT	The product is used for intensive cleaning of the sampler needle on Automated ECL Immunoassay Analyzer.	Annex VIII, Class A, Rule 5
9	High-Voltage Adjustment Buffer	380 mL 1×1 L 1×2 L	679016 0320507304 0320507303	69703416803205068JV	High-Voltage Adjustment Buffer (HVA Buffer) is used to provide and maintain electrochemical reaction environment during high-voltage adjustment testing. The major functions of High-Voltage Adjustment Buffer present as follows: ● Forming a stable surface structure on the electrode ● Transporting the reaction mixture ● Cleaning magnetic particles enveloped with immuno-complexes ● Generation electrochemilumescent signal. HVA Buffer can be used with all reagent lots.	Annex VIII, Class A, Rule 5
10	High-Voltage Adjustment Reagent	50T, 2×50T	679015 320507204	69703416803205069JX	High-Voltage Adjustment Reagent is only used for instrument calibration by Lifotronic technical service.	Annex VIII, Class A, Rule 5
11	Measuring Cell Maintenance Buffer	200 mL, 6×200 mL, 50 mL, 2×50 mL	679013 679014 0320507104 0320507105	69703416803205070JG	The product is used for maintenance of the measuring cell unit on an eCL series Automated ECL Immunoassay Analyzer.	Annex VIII, Class A, Rule 5
12	PreClean	2×800 mL 4×800 mL 2×2 L 4×2 L	0320507502 0320507503 0320507501 0320507504	69703416803205071JJ	PreClean is used to remove potentially interfering substances before signal generation - the final step of the analytical procedure. PreClean is used on ECL immunoassay analyzers in conjunction with assay reagents. PreClean can be used with all reagent lots.	Annex VIII, Class A, Rule 5
13	Sample Diluent	50 mL	0320509906	69703416803205072JL	Sample Diluent is used as a sample diluent in conjunction with Lifotronic immunoassay reagents.	Annex VIII, Class A, Rule 5
14	Assay Cup/Assay Tip	6×6×105 1×6×105	0320510001 0320510002	69703416803205085JV	Assay Cup/Assay Tip tray is intended to be used as IVD accessory for the Lifotronic automated ECL immunoassay analyzers.	Annex VIII, Class A, Rule 5

Appendix II

No.	Product Name	Specification	REF No.	Basic UDI DI	Intended Purpose	Classification
1	HbA1c Analyser	GH-900Plus, GH-900	/	6970341680120202GS	/	Annex VIII, Class A, Rule 5
2	Hemoglobin Analyzer (HPLC)	H8, H9, H100, H100Plus	/	6970341680120203GU	Hemoglobin Analyzer (HPLC) adopts High Performance Liquid Chromatography (HPLC) to measure the content of HbA1c in human blood. According to the selected protocol, the system can also measure the content of HbF and HbA2 .	Annex VIII, Class A, Rule 5
3	Eluent A	400 mL, 800 mL, 1600mL	0320200501 0320200502 0320200509	69703416803202038HX	The Eluent A used together with Eluent B,Eluent C and Eluent D is intended for quantitative examination of HbA2, HbF or/and HbA1c in the whole blood of human body with Lifotronic Hemoglobin Analyzer automatically using High Performance Liquid Chromatography (HPLC).	Annex VIII, Class A, Rule 5
4	Eluent B	400 mL, 800 mL	0320200503 0320200504	69703416803202039HZ	The Eluent B used together with Eluent A,Eluent C and Eluent D is intended for quantitative examination of HbA2, HbF or/and HbA1c in the whole blood of human body with Lifotronic Hemoglobin Analyzer automatically using High Performance Liquid Chromatography (HPLC).	Annex VIII, Class A, Rule 5
5	Eluent C	400 mL, 800 mL	0320200505 0320200506	69703416803202040HJ	The Eluent C used together with Eluent A,Eluent B and Eluent D is intended for quantitative examination of HbA2, HbF or/and HbA1c in the whole blood of human body with Lifotronic Hemoglobin Analyzer automatically using High Performance Liquid Chromatography (HPLC).	Annex VIII, Class A, Rule 5
6	Eluent D	400 mL, 800 mL, 1600mL	0320200507 0320200508 0320200528	69703416803202041HL	The Eluent D used together with Eluent A,Eluent B and Eluent C is intended for quantitative examination of HbA2, HbF and HbA1c in the whole blood of human body with Lifotronic Hemoglobin Analyzer automatically using High Performance Liquid Chromatography (HPLC).	Annex VIII, Class A, Rule 5
7	Eluent A	400 mL, 800 mL, 1600mL	0320202704 0320202705 0320202706	69703416803202042HN	The Eluent A used together with Eluent B,Eluent C and Eluent D is intended for quantitative examination of HbA1c in the whole blood of human body with Lifotronic Hemoglobin Analyzer automatically using High Performance Liquid Chromatography (HPLC).	Annex VIII, Class A, Rule 5
8	Eluent B	400 mL, 800 mL	0320202803 0320202804	69703416803202043HQ	The Eluent B used together with Eluent A,Eluent C and Eluent D is intended for quantitative examination of HbA1c in the whole blood of human body with Lifotronic Hemoglobin Analyzer automatically using High Performance Liquid Chromatography (HPLC).	Annex VIII, Class A, Rule 5
9	Eluent C	400 mL, 800 mL	0320202903 0320202904	69703416803202044HS	The Eluent C used together with Eluent A,Eluent B and Eluent D is intended for quantitative examination of HbA1c in the whole blood of human body with Lifotronic Hemoglobin Analyzer automatically using High	Annex VIII, Class A, Rule 5

					Performance Liquid Chromatography (HPLC).	
10	Eluent D	400 mL, 800 mL, 1600mL	0320203004 0320203005 0320203006	697034168032 02045HU	The Eluent D used together with Eluent A,Eluent B and Eluent C is intended for quantitative examination of HbA1c in the whole blood of human body with Lifotronic Hemoglobin Analyzer automatically using High Performance Liquid Chromatography (HPLC).	Annex VIII, Class A, Rule 5
11	Hemolytic Agent L	2500 mL, 5000 mL	0320200401 0320200402	697034168032 02024HL	The Hemolytic Agent L is intended for pre-treatment of blood samples of human body with Lifotronic Hemoglobin Analyzer.	Annex VIII, Class A, Rule 5
12	Probe Rinse Solution	30 mL, 50 mL, 5 mL×5	0320201203 0320201204 0320201207	697034168032 02025HN	Probe Rinse Solution is used for cleaning and flushing the injector and liquid circuit system of Hemoglobin Analyzer.	Annex VIII, Class A, Rule 5
13	THALASSAEMIA & HbA1c Reagent Kit (HPLC)	200T, 400T	0320201205 0320201206	697034168032 02026HQ	The kit is for isolation of HbA2、HbF and HbA1c from human specimens and is used for quantitative determination of HbA2、HbF and HbA1c content in the whole blood of human body with the beta-thalassemia analysis mode on Lifotronic Hemoglobin Analyzer by high performance liquid chromatography (HPLC) method. This result can be used for reference of clinical β-thalassaemia diagnosis.	Annex VIII, Class A, Rule 5
14	ß-THALASSAEMIA & HbA1c Reagent Kit (HPLC)	200T/box	0320201205	697034168032 02027HS	The kit is for isolation of HbA2、HbF and HbA1c from human specimens and is used for quantitative determination of HbA2、HbF and HbA1c content in the whole blood of human body with the beta-thalassemia analysis mode on Lifotronic Hemoglobin Analyzer by high performance liquid chromatography (HPLC) method. This result can be used for reference of clinical β-thalassaemia diagnosis.	Annex VIII, Class A, Rule 5
15	HbA1c Reagent Kits (HPLC)	100T, 200T, 400T	0320201001, 0320201002, 0320201003	697034168032 02029HW	The kit is for isolation of HbA1c from human specimens and is used to quantitative determination of HbA1c content in the whole blood of human body with Lifotronic HbA1c/Hemoglobin Analyzer by high performance liquid chromatography (HPLC) method. HbA1c has a stable structure, of which in vivo synthesis process is slow and irreversible. The synthesis rate of HbA1c is proportional to the concentration of blood glucose. It accumulates in the erythrocytes of 120 days lifetime. Therefore, the level of HbA1c reflects the average level of blood glucose in the past 2~3 months. It's a reliable biomarker to indicate blood glucose levels.	Annex VIII, Class A, Rule 5