



EC DECLARATION OF CONFORMITY



PRODUCT IDENTIFICATION				
Product Name	Model	EMDN	Basic UDI-DI	Registration Number
Urine Analyzer	H-100	W020101020102	69257945W020101020102D0B3	NL-CA002-2023-75374
	HC-300	W020101020102	69257945W020101020102D0B3	NL-CA002-2023-75374
	H-500	W020101020102	69257945W020101020102D0B3	NL-CA002-2023-75374
	H-800	W020101020103	69257945W020101020103D0B8	NL-CA002-2023-75374
	H-1600	W020101020103	69257945W020101020103D0B8	NL-CA002-2023-75374
Semi-automatic Chemistry Analyzer	DR-7000D	W0201010101	69257945W0201010101D0JF	NL-CA002-2022-68043
Auto-Chemistry Analyzer	CS-T240	W0201010101	69257945W0201010101D0JF	NL-CA002-2022-68044
	CS-300B	W0201010101	69257945W0201010101D0JF	NL-CA002-2022-72961
	CS-T180	W0201010101	69257945W0201010101D0JF	NL-CA002-2022-72962
	CS-T240Plus	W0201010101	69257945W0201010101D0JF	NL-CA002-2022-72963
	CS-400	W0201010101	69257945W0201010101D0JF	NL-CA002-2022-72964
	CS-480	W0201010101	69257945W0201010101D0JF	NL-CA002-2022-72965
	CS-680	W0201010102	69257945W0201010102D0JL	NL-CA002-2022-72966
	CS-1200	W0201010102	69257945W0201010102D0JL	NL-CA002-2022-72967
	CS-1300B	W0201010103	69257945W0201010103D0JR	NL-CA002-2022-72968
	CS-1600	W0201010103	69257945W0201010103D0JR	NL-CA002-2022-72969
	CS-2000	W0201010104	69257945W0201010104D0JW	NL-CA002-2022-72970
	CS-2000i	W0201010104	69257945W0201010104D0JW	NL-CA002-2022-72971
	CS-600B	W0201010102	69257945W0201010102D0JL	NL-CA002-2022-72972
Chemiluminescence Immunoassay Analyzer	CM-180	W0201020102	69257945W0201020102D0K5	NL-CA002-2022-68040
	CM-320	W0201020104	69257945W0201020104D0KF	NL-CA002-2022-68041
	CM-320i	W0201020103	69257945W0201020103D0KA	NL-CA002-2022-68042

	CM-640i	W0201020103	69257945W0201020103D0KA	NL-CA002-2022-73342
	CM-640	W0201020104	69257945W0201020104D0KF	NL-CA002-2022-73341
Automatic Blood Coagulation Analyzer	BCA-1000	W0202020102	69257945W0202020102D0KU	NL-CA002-2022-68045
	BCA-2000	W0202020102	69257945W0202020102D0KU	NL-CA002-2023-77944
	BCA-3000	W0202020102	69257945W0202020102D0KU	NL-CA002-2022-68046
	BCA-4000	W0202020102	69257945W0202020102D0KU	NL-CA002-2022-73340
Automated Hematology Smear Slide Processor	BSP-800	W0202059002	69257945W0202059002D0QR	NL-CA002-2022-68047
Sample Processing System	LA-60	W02060101	69257945W02060101D0YE	NL-CA002-2022-68051
	LA-60SE	W02060101	69257945W02060101D0YE	NL-CA002-2024-78888
	LA-90	W02060101	69257945W02060101D0YE	NL-CA002-2024-78888

MANUFACTURER

Name of Company	Address	Person Responsible for Regulatory Compliance	SRN
DIRUI INDUSTRIAL CO., LTD.	95 Yunhe Street New & High Tech. Development Zone Changchun, Jilin 130012 P.R. China	He Haohui	CN-MF-000001891

AUTHORIZED REPRESENTATIVE

Name of Company	Address	SRN
SUNGO Europe B.V.	Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands	NL-AR-000000247

CONFORMITY ASSESSMENT

Device Classification	Route to Compliance
Class: A	Regulation(EU) 2017/746 of the European Parliament and of the Council: Rule 5b - Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures

Applicable Standards

EN ISO 20417: 2021

EN ISO 15223-1:2021

EN ISO 18113-1:2011

EN ISO 18113-3:2011

EN ISO 14971:2019

Conformity Assessment

Compliance of the designated products with the Regulation(EU) 2017/746 of the European Parliament and of the Council has been assessed by issuing the EU declaration of conformity referred to in Article 17 after drawing up the technical documentation set out in Annexes II and III.

Declaration

DIRUI INDUSTRIAL CO., LTD. hereby declares that the above mentioned products meet the provisions of the Regulation(EU) 2017/746 of the European Parliament and of the Council; and the EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Person Responsible for Regulatory Compliance: He Haohui

Title: General Manager of Testing Center

Date: 6th May, 2024

