



EC DECLARATION OF CONFORMITY



PRODUCT IDENTIFICATION

Product Family Name	Product Name	Basic UDI-DI	EMDN	Registration No.
Chemistry Reagent	CS-Anti-Bacterial Phosphor-Free Detergent	69257945W01019099R04Y	W01019099	NL-CA002-2022-67053
	CS-Alkaline Detergent	69257945W01019099R04Y	W01019099	NL-CA002-2022-67054
	CS-ISE Detergent	69257945 W01010399R02C	W01010399	NL-CA002-2022-67056
	ISE Diluent	69257945W01010399R02C	W01010399	NL-CA002-2022-67055
Hematology Reagent	Cleanser	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67057
	B-Z Cleanser	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67058
	Probe Cleanser(BCC-3000)	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67059
	Diluent	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67060
	BF Detergent	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67061
	BF-Diluent	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67062
	BF-5D Diluent	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67070
	BCC-3D Diluent	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67064
	Probe Cleanser I	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67065
	Probe Cleanser	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67066

	BF-5D-I Diluent	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67067
	BF-RD Diluent	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67068
	BF-WFF Dye	69257945W0103010199R0PF	W0103010199	NL-CA002-2022-67121
	BF-RF Dye	69257945W0103010199R0PF	W0103010199	NL-CA002-2022-67122
	BF-WNF Dye	69257945W0103010199R0PF	W0103010199	NL-CA002-2022-67123
	BCC-3000 Cleanser	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67069
	Diluent(BCC-3000)	69257945W0103010105R0LU	W0103010105	NL-CA002-2022-67071
Urinalysis Reagent	H Series Urine Analyzer Cleaning Liquid for Refractometer and Turbidimeter	69257945W0101060299R0QZ	W0101060299	NL-CA002-2022-67072
	Cleaning liquid (Concentrated type)	69257945W0101060299R0QZ	W0101060299	NL-CA002-2022-67073
	Urine Sediment Analyzer Reagent Diluent	69257945W010106020302R0FD	W010106020302	NL-CA002-2022-67096
	Urine Sediment Analyzer Reagent Sheath	69257945W010106020302R0FD	W010106020302	NL-CA002-2022-67097
	Sheath	69257945W010106020302R0FD	W010106020302	NL-CA002-2022-67098
	FUS Series Urinalysis Hybrid Sheath II	69257945W010106020302R0FD	W010106020302	NL-CA002-2022-67099
	Urine Sediment Analyzer Detergent	69257945W0101060299R0QZ	W0101060299	NL-CA002-2022-67101
	Disposable Urine Tube	69257945W05010202R0ZQ	W05010202	NL-CA002-2022-67102
	Cleaning liquid II (Concentrated type)	69257945W0101060299R0QZ	W0101060299	NL-CA002-2022-67100
Chemiluminescence	Alkaline Trigger Reagent	69257945W01029099R05H	W01029099	NL-CA002-2022-67103

Immunoassay Reagent	Acid Trigger Reagent	69257945W01029099R05H	W01029099	NL-CA002-2022-67104
	Concentrated Washing Buffer	69257945W01029003R02L	W01029003	NL-CA002-2022-67105
	Sample Pretreatment Reagent	69257945W01029003R02L	W01029003	NL-CA002-2022-67106
	RBC Folate Releasing Agent	69257945W01029003R02L	W01029003	NL-CA002-2022-67107
	Probe Washing Buffer	69257945W01029099R05H	W01029099	NL-CA002-2022-67108
	Probe Conditioning Solution	69257945W01029099R05H	W01029099	NL-CA002-2022-67111
	Sample Diluent	69257945W01029003R02L	W01029003	NL-CA002-2022-67119
Vaginal Secretions Analysis Reagent	Vaginal Infections Analysis Detergent	69257945W01019099R04Y	W01019099	NL-CA002-2022-67112
	Cell Preservation Liquid	69257945W01019099R04Y	W01019099	NL-CA002-2022-67113
	FE Dye	69257945W01030702R0ZM	W01030702	NL-CA002-2022-67116
	FE Laminar Liquid	69257945W01019099R04Y	W01019099	NL-CA002-2022-67114
	Disposable Sampler	69257945W05019099R07U	W05019099	NL-CA002-2022-67115
Blood Coagulation Reagent	Automatic Blood Coagulation Analyzer Detergent I	69257945W0103020999R0SQ	W0103020999	NL-CA002-2022-67117
	Automatic Blood Coagulation Analyzer Detergent II	69257945W0103020999R0SQ	W0103020999	NL-CA002-2022-67118
	Sample Diluent	69257945W0103020903R0PT	W0103020903	NL-CA002-2022-67120

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.	Fascinatia 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 18113-2:2011

EN ISO 14971:2019

Conformity Assessment

Compliance of the designated product with the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 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 provision of the Regulation (EU) 2017/746 of the European Parliament; and the EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Person Responsible for Regulatory Compliance: He Haohui

Title: Deputy General Manager Signature: He Haohui

Date: June 13, 2023

