



GIÁM ĐỐC

Cao Xuân Dũng

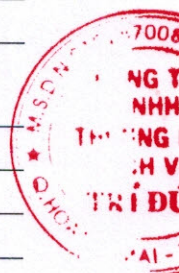


EC DECLARATION OF CONFORMITY



PRODUCT IDENTIFICATION

Product Family Name	Product Name	Registration Number
Reagent for Hematology Analyzer	BF-FDTI Lyse	NL-CA002-2018-45404
	BF-FDOI Lyse	
	BF-5D Diluent	
	BCC-3D Diluent	
	BCC-3D Lyse	
	Probe cleanser I	NL-CA002-2018-45405
	Control for Automatic Hematology Analyzer(5-Part)	NL-CA002-2015-37552
	Calibrator for hematology analyzer(5-Part)	NL-CA002-2015-37556
	Control for Automatic Hematology Analyzer(3-part)	NL-CA002-2015-37555
	BF Detergent	NL-CA002-2015-37554
	BF-Diluent	NL-CA002-2015-37553
	B-Z Cleanser	NL-CA002-2015-37559
	Cleanser	NL-CA002-2015-37560
	Diluent	NL-CA002-2015-37557
	Probe Cleanser	NL-CA002-2015-37558
	Lyse(3-part)	NL-CA002-2015-37550
	BF-6500 Lyse SLS-I	NL-CA002-2015-37545
	BF-FBA Lyse	NL-CA002-2015-37547
	BF-FDO Lyse	NL-CA002-2015-37549
BF-FDT Lyse	NL-CA002-2015-37548	
BF-SLS Lyse	NL-CA002-2015-37546	
Blood Sample Calibrator	NL-CA002-2018-45404	
BF-FBH Lyse	NL-CA002-2019-45901	
BF-CRP Lyse		
C-REACTIVE PROTEIN KIT	NL-CA002-2021-56543	
Fluorescent Control		
Fluorescent Calibrator		
Control for Reticulocyte		
Control for Body Liquid		
BF-5D-I Diluent		
BF-RD Diluent		



Reagent for Hematology Analyzer	BF-WFF Dye	NL-CA002-2021-56543
	BF-RF Dye	
	BF-WNF Dye	
	BF-WFL Lyse	
	BF-WNL Lyse	
	BF-SLS-II Lyse	

MANUFACTURER

Name of Company	Address	Representative
Dirui Industrial Co., Ltd.	95 Yunhe Street New & High Tech. Development Zone Changchun, Jilin 130012 P.R. China	Zheng Guoming

AUTHORIZED REPRESENTATIVE

Name of Company	Address	Telephone/E-mail
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CONFORMITY ASSESSMENT

Device Classification	Route to Compliance
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive

Dirui Industrial Co., Ltd. hereby declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for in vitro diagnostic medical devices and Directive 98/79/EC as transposed in the national laws of the Member States.

Company representative: Zheng Guoming

Title: General Manager Signature:

Date: March 18, 2021

