



GIÁM ĐỐC

Cao Xuân Dũng

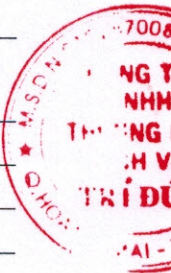


EC DECLARATION OF CONFORMITY



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 | |



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|---------------------------------|----------------|---------------------|
| 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 |
|-----------------|--|---|
| Emergo Europe | Prinsessegracht 20 2514 AP The Hague The Netherlands | Tel: +31.70.345.8570 EmergoEurope@ul.com |

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

