DECLARATION OF CONFORMITY

MANUFACTURER:	Shenzhen Dymind Biotechnology Co., Ltd. 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107, P. R. China
MEDICAL DEVICE:	Product: Auto Hematology Analyzer Model: DF50, DF51, DF52, DF53, DF55, DF56
CLASSIFICATION:	OTHERS, The device not in IVDD annex II and not for self testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Auto Hematology Analyzer STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. EN13612:2002; EN ISO13485:2016; EN ISO 9001:2015; EN ISO14971:2012; EN/IEC 61010-1:2010;IEC 61010-2-101:2015/EN 61010-2-101:2017; EN/IEC 61010-2-081:2015; EN 61326-1:2013/IEC 61326-1:2012; EN 61326-2-6:2013/IEC 61326-2-6:2012; EN ISO 18113-1:2011; EN ISO 18113-3:2011; EN ISO15223-1:2016.*

European Representative: Eunitor GmbH
Kennedydamm 5, 40476 Duesseldorf, Germany

ISSUE DATE: 2021-7-7

PLACE, DATE OF DECLARATION: *SHENZHEN*

SIGNATURE: Pingyi Ren

NAME: PINGYI REN
POSITION: REGULATORY AFFAIR DIRECTOR

深圳市帝迈生物技术有限公司

Digitally signed by Bolea Petru
Date: 2023.11.21 10:57:03 EET
Reason: MoldSign Signature
Location: Moldova