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
IMPORTER:	Lazzaned Group Srl Largo Iv Novembre 11 Ponte San Pietro BG 24036, Italy
MEDICAL DEVICE:	Product: Auto Hematology Analyzer Trade mark: LAZZANED GROUP Model: EMATO 4.0
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 61010-1:2010+A1:2019; EN 61010-2-101:2017; EN 61010-2-081:2015; EN 61010-2-010: 2014; EN 61326-1:2020; EN 61326-2-6:2020; ETSI EN 300 330 V2.1.1(2017-02); ETSI EN 301 489-1 V2.2.3(2019-11); ETSI EN 301 489-3 V2.2.1(2019-03); EN 50364:2018; EN 62369-1: 2009(TEST METHOD); EN ISO 18113-1:2011; EN ISO 18113-3:2011; EN ISO15223-1:2016; EN591:2001; ISTA 2A:2011.*

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PLACE, DATE OF DECLARATION: *SHENZHEN*

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SIGNATURE:

NAME: PINGYI REN
POSITION: REGULATORY AFFAIR DIRECTOR