

EC Declaration of Conformity

according to the Directive 98/79/EC (applicable to **Others** *IVD* Devices only)

Manufacturer: Labnovation Technologies, Inc.

101 and 5th Floor, Building 1, No. 68,18th Road, Guangming

Hi-Tech Park, Tangjia Community, Fenghuang Street, Guangming District, Shenzhen 518057, Guangdong, China

European Authorised: MedNet EC-REP GmbH

Representative: Borkstrasse 10.48163 Muenster. Germany

Product/s: Automated HbA1c Analyzer and the Test Kit for Use on

Components: See the attachment system Model / Specification: See the attachment system

Classification: Others/General

Conformity assessment route: Annex III, except point 6, of Directive (Module A)

IVDD Annex Ⅲ

We 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.

Signed on 01 / (Day) 08 / (Month) of 2024 Place She

Place Shenzhen, China

Represented by

Signature (on behalf of the manufacturer)

Full Name of authorized signatory: Wang Min

Position held in the company: General Manager

Attachment system

Components Name	Model / Specification
Automated HbA1c Analyzer	LD-560
Glycosylated Hemoglobin Test Reagent Kit	800 Tests; 600Tests; 400 Tests; 200 Tests.
HbA1c Calibrator kit	Level 1: 0.1mL×3, Level 2: 0.1mL×3
	Level 1: 0.1mL×4, Level 2: 0.1mL×4
	Level 1: 0.1 mL×6, Level 2: 0.1 mL×6
	Level 1: 0.5 mL×2, Level 2: 0.5 mL×2
	Level 1: 0.5mL×4, Level 2: 0.5mL×4
	Level 1: 0.5mL×6, Level 2: 0.5mL×6
HbA1c Control kit	Level 1: 0.1mL×3, Level 2: 0.1mL×3
	Level 1: 0.1mL×4, Level 2: 0.1mL×4
	Level 1: 0.1mL×6, Level 2: 0.1mL×6
	Level 1: 0.5mL×2, Level 2: 0.5mL×2
	Level 1: 0.5mL×4, Level 2: 0.5mL×4
	Level 1: 0.5mL×6, Level 2: 0.5mL×6