TÜVRheinland®

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2095583-1

Manufacturer: Andon Health Co., Ltd.
No. 3 Jinping Street
YaAn Road, Nankai District
300190 Tianjin
P.R. China

Products: Blood Glucose Monitoring Systems Consisting of Blood Glucose Meters, Blood Glucose Test Strips and Control Solutions, Digital Pregnancy Tests, Digital Ovulation Tests, Digital Pregnancy and Digital Ovulation Tests, Pregnancy Test Strips, Ovulation Test Strips
Replaces Approval, Registration No.: HL 60144497 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 244412056-200

Effective date: 2022-05-21

Expiry date: 2025-05-26

Issue date: 2022-05-21

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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YaAn Road, Nankai District
300190 Tianjin
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location
/01	Andon Medical Co ., Ltd. No.26 HangYu Road, Tianjin Airport Economic Area, 300380 Tianjin P.R. China

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