EC Certificate

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

Registration No.: HL 60151218 0001

Report No.: 16804223 008

Manufacturer:

Yercon Diagnostic Co., Ltd.
No.2 Building, Ledong Industrial Estate 3248
Century Ave.
Tech. & Economic Development Zone
130032 Changchun, Jilin
P.R. China

Products:

In-vitro Diagnostic Reagent Strips for Self-testing used for Urinalysis

Replaces Approval, Registration No.: HL 60146984 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex IV, excluding section 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.

Effective Date: 2020-09-27

Date: 2020-09-27

Notified Body

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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.