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 60098575 0001

Report No.: 16804223 001

Manufacturer:
Yercon Diagnostic Co., Ltd.
2058 Pudong Road
Economic & Tech. Development Zone
130033 Changchun
China

Products:
In-vitro diagnostic reagent strips for self-testing used for urinalysis

Expiry Date: 2020-03-01

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: 2015-03-31

Date: 2015-03-31

Notified Body

Dipl.-Ing. C. Wiora

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.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Genau. Richtig.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Yercon Diagnostic Co., Ltd.
2058 Pudong Road
Economic & Tech. Development Zone
130033 CHANGCHUN
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date March 31, 2015

Application for : **Vollst. QMS, Anhang IV, IVD**
Certificate No. : HL 60098575 Sheet 0001
Device : Only for QM-System audit
Test requirement : 98/79/EG

Dear Madame or Sir,

Enclosed please find the
new certificate No. HL 60098575 0001.

Kind regards

Certification body

Dipl.-Ing. C. Wiora

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nürnberg HRB 26013
UST-ID Nr.: DE 811835490