

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer : **Guilin Royalyze Medical Instrument Co., Ltd.**
18 Li River Road, Qixing District, Guilin 541004 Guangxi
P.R.China

European representative: **Caretechion GmbH**
Niederrheinstr. 71, 40474 Duesseldorf, Germany

We declare under our sole responsibility that

the in vitro diagnostic medical device: **Blood Glucose Test Strips Model:BG01**
Uric Acid Test Strips Model: UA01
Total Cholestrol Test Strips Model: TC01

of class: **List B**
according to annex II of directive 98/79/EC

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it.
The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 98/79/EC Annex IV, excluding Section 4**

Registration No.:/ **HL 2156856-1**

Notified Body: **TÜV Rheinland LGA Products GmbH**
Tillystraße 2 · 90431 Nürnberg · Germany
CE 0197



Guilin, 2022-06-16

Place, date

Mrs. Shan Liao, QMR

Name and function

The technical documentation is filed at: Guilin Royalyze Medical Instrument Co., Ltd.