EC DECLARATION OF CONFORMITY

Name and address of the manufacturer :	**Guilin Royalyze Medical Instrument Co., Ltd.** 1st Floor No. 13, Lushan Road, Lingui District, Guilin 541199 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: **Multi-Monitoring Meter**

Model: LBM-01

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
Issue date: 2022.03.22
Expiry date: 2025.05.26
Transition date:2028.12.31

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany
CE 0197

GUILIN ROYALYZE MEDICAL INSTRUMENT CO.,LTD 桂林乐尔医疗器械有限公司 4503060000635

Guilin, 2025-11-06
Place, date

Liao Shan , MR
Name and function

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

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer :	**Guilin Royalyze Medical Instrument Co., Ltd.** 1st Floor No. 13, Lushan Road, Lingui District, Guilin 541199 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: **Hemoglobin Test Strips**

Model: HB01

Of class: Self-testing

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**
Issue date: 2022.03.22
Expiry date: 2025.05.26
Transition date:2028.12.31

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

GUILIN ROYALYZE MEDICAL INSTRUMENT CO., LTD. 桂林乐尔医疗器械有限公司 4503060000635

Guilin, 2025-11-06
Place, date

Liao Shan , MR
Name and function

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

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer :	**Guilin Royalyze Medical Instrument Co., Ltd.** 1st Floor No. 13, Lushan Road, Lingui District, Guilin 541199 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

Of class: Self-testing

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
Issue date: 2022.03.22
Expiry date: 2025.05.26
Transition date:2028.12.31

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany
CE 0197

GUILIN ROYALYZE MEDICAL INSTRUMENT CO.,LTD 桂林乐尔医疗器械有限公司 4503060000635

Guilin, 2025-11-06
Place, date

Liao Shan , MR
Name and function

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

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer :	**Guilin Royalyze Medical Instrument Co., Ltd.** 1st Floor No. 13, Lushan Road, Lingui District, Guilin 541199 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: **Total Cholesterol Test Strips**

Model: TC01

Of class: Self-testing

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
Issue date: 2022.03.22
Expiry date: 2025.05.26
Transition date:2029.12.31

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany
CE 0197

GUILIN ROYALYZE MEDICAL INSTRUMENT CO.,LTD 桂林乐尔医疗器械有限公司 4503060000635

Guilin, 2025-11-06
Place, date

Liao Shan , MR
Name and function

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

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer :	**Guilin Royalyze Medical Instrument Co., Ltd.** 1st Floor No. 13, Lushan Road, Lingui District, Guilin 541199 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: **Uric Acid Test Strips**

Model: UA01

Of class: Self-testing

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
Issue date: 2022.03.22
Expiry date: 2025.05.26
Transition date:2028.12.31

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany
CE 0197

Guilin, 2025-11-06
Place, date

Liao Shan , MR
Name and function

GUILIN ROYALYZE MEDICAL INSTRUMENT CO.,LTD 桂林乐尔医疗器械有限公司 4503060000635

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