



National Institute of Medical Device Safety Information

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Certificate of Free Sales

No. of Certificate : 20230111715

- Exporting(certifying) country : Republic of Korea
- Importing(requesting) country : Vietnam

The National Institute of Medical Device Safety Information, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act, and the following product(s) is(are) permitted to be freely sold in domestic and overseas markets.

○ Applicant (=Product-license holder)

(This certificate shall not be issued to others than the product-license holder)

- Name : GC MEDIS Corp.
- Address : 16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31045, Rep. of Korea
- Registered No : Manufacturer IVD-2454

No. and date of product-license, comments	Classification
IVD-14-2419 / NOV. 24. 2014	IVD reagents for diabetes mellitus [2]
IVD-14-2422 / NOV. 24. 2014	IVD reagents for diabetes mellitus [2]

※ Attached, if necessary (approved product information)

- Model(Export Name)
- Medical Device Accessories
- Manufacturer/Legal manufacturer
- Combined/Composite medical device

Issued date : JUL. 05. 2023 (Certificate No.20230111715)

Certified by

Director of Medical Device Certification Department
National Institute of Medical Device Safety Information

The National Institute of Medical Device Safety Information(NIDS) is related organization of Ministry of Food and Drug Safety and established under Article 42 of the Medical Device Act.

The Minister of Food and Drug Safety authorized the director of NIDS to issue this free sales certificate under the Article 44



※ This certificate has been issued on the Internet, you can check whether to forge or modify by the issued number. Furthermore, You can also check it by barcode exploiting document check program for scanner

Attachment

Product License No. : IVD-14-2419 (APR. 19. 2021)

Classification : IVD reagents for diabetes mellitus

Model(Export Name)

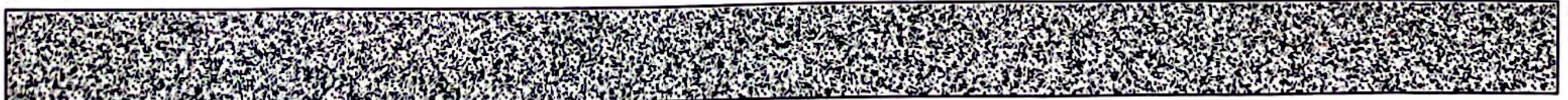
- Labonacheck A1c HbA1c Test Kit

Product License No. : IVD-14-2422 (JUN. 23. 2020)

Classification : IVD reagents for diabetes mellitus

Model(Export Name)

- CERA-STAT 2000 HbA1c Test Kit



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Certificate of Authentication

Seen at the Ministry of Foreign Affairs of the Republic of Korea.
Valid only if submitted to foreign missions in the Republic of Korea.

1. Country : Republic of Korea



Certified

To verify the Certificate, please refer to the website below.
<https://www.apostille.go.kr>

2. at Seoul 3. the 11/07/2023

4. by The Ministry of Foreign Affairs


5. No. XXC2023C27S8AC

6. Seal/stamp

7. Signature

Jeong Hyo Youn




ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI HÀN QUỐC
THE EMBASSY OF THE SOCIALIST REPUBLIC OF VIETNAM IN THE REPUBLIC OF KOREA

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia Việt Nam
Country Vietnam

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) Jeong Hyo Youn ký
has been signed by

3. với chức danh Viên chức lãnh sự
acting in the capacity of

4. và con dấu của Bộ Ngoại giao Hàn Quốc
bears the seal/stamp of Ministry of Foreign Affairs of the Republic of Korea


được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại Hàn Quốc 6. ngày 12/07/2023
at The Republic of Korea on

7. Cơ quan cấp Đại sứ quán nước CHXHCN Việt Nam tại Hàn Quốc
by The embassy of the S.R. of Vietnam in the Republic of Korea

8. Số 091812 CNLS/HPHLS
Signature and seal/stamp

Tham tán Công sứ / Minister Counsellor


Nguyễn Việt Anh 03819

