



National Institute of Medical Device Safety Information

#303-1, Mario Tower, 28, 30-gil, Digital-ro, Guro-gu, Seoul, Korea(08389),

Tel: +82-2-860-4450, Fax: +82-2-860-4479

Certificate of Free Sales

No. of Certificate : 20250118621

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 : OSANG Healthcare Co., Ltd.

- Address : 132 Anyangcheondong-ro, Dongan-gu, Anyang-si Gyeonggi-do

- Registered No : Manufacturer IVD-652

No. and date of product-license, comments	Classification
IVD- 24-1399 / NOV. 12. 2024	Hematology analyzer, glycohemoglobin [1] Name of Product : HemoCue HbA1c 501 Analyzer, HemoCue HbA1c 501 Daily Check Cartridge, HemoCue HbA1c 501 Monthly Check Cartridge

※ Attached, if necessary (approved product information)

Model(Export Name)

Medical Device Accessories

Manufacturer/Legal manufacturer

Combined/Composite medical device

o Do the facilities and operations conform to KGMP as recommended by the Ministry of Food and Drug Safety?

Yes

No

Issued date : JUN. 12. 2025 (Certificate No.20250118621)

Certified by

안만호

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



Attachment

Product License No. : IVD- 24-1399 (NOV. 12. 2024)

Classification : Hematology analyzer, glycohemoglobin

Model(Export Name)

-
- IGM-0026BMD
 - IGM-0026BMM
 - IGM-0026BM



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 18/06/2025

4. by The Overseas Koreans Agency

5. No. XXC2025G9N26P7

6. Seal/stamp

7. Signature

Lee Dae Young



ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI HÀN QUỐC
EMBASSY OF THE S.R. OF VIET NAM IN THE REPUBLIC OF KOREA

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

Việt Nam

1. Quốc gia.....
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) **Lee Dae Young**..... ký
has been signed by **Viên chức lãnh sự**

3. với chức danh.....
acting in the capacity of **Bộ Ngoại giao Hàn Quốc**

4. và con dấu của.....
bears the seal/stamp of

được chứng nhận / hợp pháp hóa lãnh sự

5. tại **Hàn Quốc**..... 6. ngày **23/06/2025**
Certified

at **ĐSQ nước CHXHCN Việt Nam tại Hàn Quốc**

7. Cơ quan cấp.....
by **BA-003S/CNLS/HPHLS**

8. Số.....
No

Ký tên và đóng dấu
Signature and seal/stamp
Bí thư (thư ký) / 1st Secretary



Lê Quốc Tuấn

72536