HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Ref: Vietnam 13910
غرفة التجارة العربية الايرلندية
Arab-Irish Chamber of Commerce

10th February 2022

HPRA Reference: MD22/0095

CERTIFICATE OF FREE SALE

To whom it may concern,

The Health Products Regulatory Authority (HPRA) hereby certifies that:

1) Manufacturer (as defined in the Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices) is Abbott Ireland Diagnostics Division, Lisnamuck, Co. Longford, N36E932

2) These *in vitro* diagnostic medical devices are manufactured by Abbott Ireland Diagnostics Division, Lisnamuck, Co. Longford, N36E932

3) The manufacturer has declared that the *in vitro* diagnostic medical devices specified in the attached schedule are CE marked in accordance with the Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices. These *in vitro* diagnostic medical devices may therefore be marketed and sold in Ireland.

4) Exportation of the *in vitro* diagnostic medical devices listed in the attached schedule is not prohibited.

5) The granting of this certificate is based on the information available to the HPRA on the date of issue of the certificate[1]. The HPRA does not authorise or approve any *in vitro* diagnostic medical devices prior to placing on the market. As the regulatory status of the *in vitro* diagnostic medical devices listed in the attached schedule may change, it is import that this certificate is considered in combination with the manufacturer's declaration of conformity for the *in vitro* diagnostic devices and, where applicable, the notified body certificates.

Issued to: Abbott Ireland Diagnostics Division,
Lisnamuck,
Co. Longford,
N36E932

Aoife Higgins
Medical Devices Department
Health Products Regulatory Authority

Seen for the authentication of signature/seal
of Aoife Higgins
Health Products Regulatory Authority
Signed
Position
Date 23/02/2022

This Authentication only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Authentication does not certify the content of the document for which it was issued. To verify an Authentication issued by the Ministry of Foreign Affairs in Ireland, see authentications.dfa.ie

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CFS 12185

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: **Việt Nam**
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà): **Fiona Murphy** ký
has been signed by

3. với chức danh: **Cán bộ lãnh sự**
acting in the capacity of

4. và con dấu của **Bộ Ngoại giao Ai-len**
bears the stamp of

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại **London** 6. Ngày **28/ 02/ 2022**
at *the*

7. Cơ quan cấp: Đại sứ quán Việt Nam tại VQ Anh và CH Ai-len
by

8. Số: **909**
N°

Ký tên và đóng dấu
Signature and seal/stamp
Bí thư thứ hai
Second Secretary

Nguyễn Quang Đông

gulatory framework in Europe can be found on the EU Commission website:
/health/md_sector/overview_en.

MEDICAL DEVICE SCHEDULE

JDI-DI	Product code	Device name/ product name	Notified body certificate number	Notified body certificate expiry date
038074ART0409QU	04T0920 04T0930	TOTAL BILIRUBIN 2	V12 054869 0013 Rev. 01	25/11/2026
038074ACU0405JU	04U0520	TOTAL BILIRUBIN 2	V12 054869 0013 Rev. 01	25/11/2026
038074ART0402QE	04T0220 04T0230	IRON 2	V12 054869 0013 Rev. 01	25/11/2026
038074ACT0498KJ	04T9820	IRON 2	V12 054869 0013 Rev. 01	25/11/2026
038074ARS0487R5	04S8720 04S8730	ALKALINE PHOSPHATASE 2	V12 054869 0013 Rev. 01	25/11/2026
038074ACT0483K5	04T8320 04T8330	ALKALINE PHOSPHATASE 2	V12 054869 0013 Rev. 01	25/11/2026
038074ART0403QG	04T0320 04T0330	Lactate Dehydrogenase2	V12 054869 0013 Rev. 01	25/11/2026
038074ACT0499KL	04T9920 04T9930	Lactate Dehydrogenase2	V12 054869 0013 Rev. 01	25/11/2026