

10<sup>th</sup> February 2022

HPRA Reference M022/0095

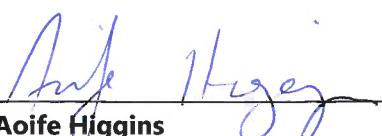
## CERTIFICATE OF FREE SALE

### 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<sup>1</sup>. 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 <u>Aoife Higgins</u> Health Products Regulatory Authority	
Signed <u>[Signature]</u>	
Position <u>[Signature]</u>	
Date <u>23/02/2022</u>	
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CONSULAR AUTHENTICATION

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*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



regulatory 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

