Ref: VIETNAM 7342

غرفة التجارة العربية الايرلندية
Arab-Irish Chamber of Commerce

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA CERTIFIED
HPRA Reference C20/1559

21st August 2020

CERTIFICATE OF FREE SALE

To Whom It May Concern

The Health Products Regulatory Authority hereby certifies that:

1) Siemens Healthcare Diagnostics Manufacturing Ltd, Chapel Lane, Swords, Co. Dublin, Ireland is the authorised representative for the in-vitro diagnostic medical devices specified in the attached schedule. These devices are manufactured by TN Michigan, 1390 Industrial Park Dr, Sault Ste. Marie, MI 49783, United States of America. Manufacturer (as defined in the in-vitro Diagnostic Medical Devices Directive 98/79/EC) is Siemens Healthcare Diagnostics Inc., 62 Flanders-Bartley Road, Flanders, NJ 07836, United States of America.

2) The in-vitro diagnostic medical devices specified in the attached schedule are CE marked in accordance with the European Communities (In-vitro Diagnostic Medical Device) Regulations, 2001 (which transposed the In-vitro Diagnostic Medical Devices Directive 98/79/EC into Irish law) and may be marketed and sold in Ireland.

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

4) The granting of this certificate is based on the information available to the Health Products Regulatory Authority on the date of issue of the certificate.

Issued To: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords
Co. Dublin
Ireland

Expiry Date: 21st August 2025

Patrick Keating
Compliance Department
Health Products Regulatory Authority

CFS011081

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire
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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 và Thương mại Ai-len**
bears the stamp of

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Certified

5. tại **London** *at* 6. Ngày **01/ 10/ 2020** *the*

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

8. Số: **3635**
N°

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

Nguyễn Quang Đông

ROINN GNOTHAI EACHTRACHA
DEPARTMENT OF FOREIGN AFFAIRS

Seen for the authentication of signature/seal
of Mr. Patrick Keating
Health Products Regulatory Authority
Signed
Position ZO
Date 18/09/2020

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MEDICAL DEVICE SCHEDULE

Item Number/Product Code	Description of Device
SMN 10385211 P/N L2ZC	IMMULITE 2000 Systems Diluent Tube Caps
SMN 10385206 P/N LRXT	IMMULITE 2000 Systems Reaction Tubes