PL

HPRA CERTIFIED
CI912383
HPRA Reference

25th October 2019

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Ref: Vietnam 3457
غرفة التجارة العربية الايرلندية
Arab-Irish Chamber of Commerce

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 Carlco Technical Plastics, Grant Road, Tucson, AZ 85705, 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: 25th October 2024

Patrick Keating
Compliance Department
Health Products Regulatory Authority

CFS010423

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CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

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Seen for the authentication of signature/seal
of Patrick Keating
Health Products Regulatory Authority
Signed Aisling Noone
Position EO
Date 08/01/2020

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MEDICAL DEVICE SCHEDULE

Item Number/Product Code	Description of Device
SMN 10385206 P/N LRXT	IMMULITE 2000 Systems Reaction Tubes