HPRA CERTIFIED
c1911671
7th August 2019
HPRA Reference

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Ref: Vietnam 3451
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 Siemens Healthcare Diagnostics Inc, 62 Flanders-Bartley Road, Flanders, NJ 07836, United States of America. Manufacturer (as defined in the in-vitro Diagnostic Medical Devices Directive 98/79/EC) is Siemens Healthcare Diagnostics Inc., 511, Benedict Avenue, Tarrytown, NY 10591, 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:** 7th August 2024

**Patrick Keating**
**Compliance Department**
**Health Products Regulatory Authority**

CFS010226



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CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
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First Secretary

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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 11066000 | Atellica IM 1600 Analyzer |
| SMN 11066001 | Atellica IM 1300 Analyzer |
| SMN 11067000 | Atellica CH 930Analyzer |
| SMN 11068008 | Atellica DL |
| SMN 11069001 | Atellica SH Prime |
| SMN 11069004 | Atellica SHAdditional |
| SMN 11069061 | Atellica Tube TopSample Cup (1ml) |
| SMN 11069062 | Atellica Tube TopSample Cup (2ml) |