HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA CERTIFIED
28th September 2021
HPRA Reference C21/1736

CERTIFICATE OF FREE SALE

To Whom It May Concern

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

1) 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) 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.

3) These *in-vitro* diagnostic medical devices are manufactured by R&D Systems, Inc., 614 McKinley Place NE Minneapolis, MN, 55413, USA

4) 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.

5) Exportation of the *in-vitro* diagnostic medical device listed in the attached schedule is not prohibited.

6) 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 device prior to placing on the market. As the regulatory status of the devices listed in the attached schedule may change, it is important that this certificate is considered in combination with the manufacturer's declaration of conformity for the devices and, where applicable, the notified body certificates.

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

Patrick Keating
Compliance Department
Health Products Regulatory Authority

CFS11912

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): **David Moloney** 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 **15/ 11/ 2021**
at *the*

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

8. Số: **5990**
N°

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

Nguyễn Quang Đông

Seen for the authentication of signature/seal
of Patraick Keating
Health Products Regulatory Authority
Signed
Position
Date 09/11/2021

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[1] An overview of the regulatory framework in Europe can be found on the EU Commission website: https://ec.europa.eu/health/md_sector/overview_en.

MEDICAL DEVICE SCHEDULE

Product Code	Device Name	HPRA Registration Number
11170852	ADVIA 360/560 Calibrator	IE/CA01/R/IV/1240/14052
11170853	ADVIA 360 Control	IE/CA01/R/IV/1240/14053
11170854	ADVIA 560 Control	IE/CA01/R/IV/1240/14054
11374312	Atellica HEMA Calibrator	IE/CA01/R/IV/1240/42739
11374313	Atellica HEMA Control	IE/CA01/R/IV/1240/42384
11374314	Atellica HEMA Control	IE/CA01/R/IV/1240/42385
11374315	Atellica HEMA Control	IE/CA01/R/IV/1240/42386
11374316	Atellica HEMA Control RETIC	IE/CA01/R/IV/1240/42387
11374317	Atellica HEMA Control RETIC	IE/CA01/R/IV/1240/42388
11374318	Atellica HEMA Control RETIC	IE/CA01/R/IV/1240/42389
11374319	Atellica HEMA Control BF	IE/CA01/R/IV/1240/42390
11374320	Atellica HEMA Control BF	IE/CA01/R/IV/1240/42391