



## 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 Diatron MI Plc, Tablas Str. 39, Budapest, Hungary H-1097. 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:** 13<sup>th</sup> August 2024

Seen for the authentication of signature/seal  
of Paulina Nulty  
Health Products Regulatory Authority  
Signed [Signature]  
Position EO  
Date 05/03/2020

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[Signature]  
**Patrick Keating**  
Compliance Department  
Health Products Regulatory Authority

CFS010229

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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): **Matthew Sewell** 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
- được chứng nhận / hợp pháp hóa lãnh sự  
Certified
5. tại **London** 6. Ngày **11/ 03/ 2020**  
at the
7. Cơ quan cấp: **Đại sứ quán Việt Nam tại VQ Anh và CH Ai-len**  
by
8. Số: **1125**  
Nº

Ký tên và đóng dấu  
Signature and seal/stamp  
Bí thư thứ nhất  
First Secretary





Nguyễn Diệu Hà

MEDICAL DEVICE SCHEDULE

<b>Item Number/Product Code</b>	<b>Description of Device</b>
SMN 11170841	ADVIA 360 Hematology System
SMN 11170842	ADVIA 560 Hematology System
SMN 11170843	ADVIA Autoloader
SMN 11170845	ADVIA 360/560 Dil
SMN 11170846	ADVIA 560 Lyse
SMN 11170847	ADVIA 560 5P Diff
SMN 11170848	ADVIA 360 Lyse 3P Diff
SMN 11170849	ADVIA 360 Cleaner
SMN 11170850	ADVIA 360/560 Hypoclean
SMN 11170851	ADVIA 360/560 Hypoclean CC