



Đại sứ quán nước CHXHCN Việt Nam tại Hoa Kỳ
Embassy of the S.R of Vietnam in the United States of America

CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia
Country

Việt Nam
Vietnam

Giấy tờ, tài liệu này
This public document

2. do Ông/Bà
has been signed by

CESAR A. PEREZ ký

3. với chức danh:
acting in the capacity of

Giám đốc Trung tâm thiết bị và phóng xạ trong y tế
Director of Center of Devices and Radiological Health

4. và con dấu của
bears the seal/stamp of

Bộ Y tế và Dịch vụ nhân sinh
Department of Health and Human Services

được chứng nhận/hợp pháp hóa lãnh sự
Certified

5. tại Washington D.C, Hoa Kỳ
at Washington D.C

6. Ngày 20 tháng 3 năm 2024
the (dd/mm/yy)

7. Cơ quan cấp: Đại sứ quán nước CHXHCN Việt Nam tại Hoa Kỳ
By Embassy of the S.R of Vietnam in the United States of America

8. Số/No. **192-03/2024-HPH**

TL. Đại sứ/ For the Ambassador
Tham tán/ Counsellor



NGUYỄN QUANG MINH

Giấy Chứng nhận số: 218-10-2023

CHỨNG NHẬN VỚI CHÍNH PHỦ NƯỚC NGOÀI

Nhằm để cho phép các sản phẩm của Hoa Kỳ lưu hành ở nước ngoài, Cục Quản lý Dược và Thực phẩm Hoa Kỳ (FDA) xác nhận các thông tin sau liên quan đến các sản phẩm xuất khẩu được liệt kê dưới đây:

Tên của Sản phẩm

Xem danh sách kèm theo
(06 trang)

Tên, địa chỉ của Nhà sản xuất/Nhà phân phối

Xem danh sách kèm theo
(01 trang)

Các sản phẩm mô tả ở trên (và các địa chỉ Nhà sản xuất/Nhà phân phối sản phẩm) thuộc thẩm quyền của FDA theo Đạo Luật Liên bang về Dược phẩm, Thực phẩm và Mỹ phẩm.

Các sản phẩm nêu trên được chứng nhận để đưa vào tiếp thị và xuất khẩu hợp pháp từ Hoa Kỳ ở thời điểm này. Các nhà máy sản xuất các sản phẩm này phải chịu sự kiểm tra định kỳ. Kỳ kiểm tra cuối cùng cho thấy ở thời điểm này, nhà máy đã tuân thủ tốt, theo đúng yêu cầu hoạt động sản xuất hiện hành cho các sản phẩm nêu trên.

Trân trọng,

(đã ký)

CESAR A. PEREZ, PhD, Giám đốc

DRP2: Phòng hỗ trợ thành lập

Văn phòng pháp lý

Văn phòng đánh giá chất lượng sản phẩm

Trung tâm thiết bị và y tế

Cục Quản lý Thực phẩm và Dược phẩm Hoa Kỳ

Giấy chứng nhận này có hiệu lực từ ngày 10/10/2023 đến ngày 09/10/2025.

Chứng thực ông Lê Anh Tuấn, Bí thư thứ Nhất, Đại sứ quán CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, đã ký trước mặt tôi.

Ngày 20 tháng 03 năm 2024

TL. Đại sứ

Tham tán



Nguyễn Quang Minh

Tôi, Lê Anh Tuấn, Bí thư thứ Nhất, Đại sứ quán CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, cam đoan đã dịch chính xác văn bản này từ tiếng Anh sang tiếng Việt.

Ngày 20 tháng 03 năm 2024

Người dịch

Lê Anh Tuấn

Certificate No. 218-10-2023

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Six Pages)

Name of Manufacturer/Distributor, Address

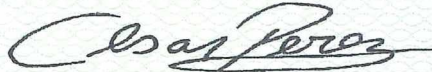
See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,



CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from October 10, 2023 to October 09, 2025.





Certificate No. 218-10-2023

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Legal Manufacturer

Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown, NY
USA 10591

Manufacturing Site

Siemens Healthcare Diagnostics Inc.
333 Coney Street
E Walpole, MA
USA 02032

Manufacturing Site

Siemens Healthcare Diagnostics Inc.
62 FLANDERS-BARTLEY RD.
FLANDERS, NJ
USA 07836

Manufacturing Site

AXIS-SHIELD DIAGNOSTICS, LTD.
LUNA PLACE
THE TECHNOLOGY PARK
DUNDEE, Scotland
UNITED KINGDOM DD2 1XA

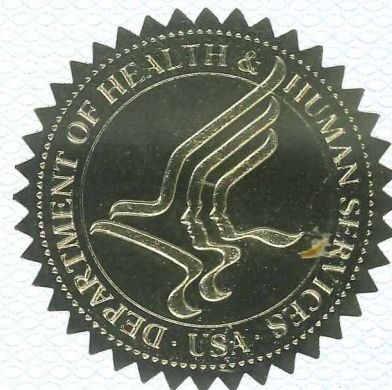
Manufacturing Site

Siemens Healthcare Diagnostics Manufacturing Ltd.
CHAPEL LANE
SWORDS, Dublin
IRELAND

Manufacturing Site

SIEMENS HEALTHCARE DIAGNOSTICS INC.
500 GBC DR, PO Box 6101
NEWARK, DE
USA 19714

----END OF MANUFACTURER/DISTRIBUTOR LIST----





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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 6

Name of Manufacturer

Legal Manufacturer

Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown, NY
USA 10591

Manufacturing Site

Siemens Healthcare Diagnostics Inc.
62 FLANDERS-BARTLEY RD.
FLANDERS, NJ
USA 07836

Manufacturing Site

Siemens Healthcare Diagnostics Manufacturing Ltd.
CHAPEL LANE
SWORDS, Dublin
IRELAND

Name of Product(s)

Atellica™ Solution
11066001 Atellica IM Analyzer (Atellica IM 1300)
11066000 Atellica IM Analyzer (Atellica IM 1600)
11068008 Atellica DL (Direct Load)
11069004 Atellica Sample Handler (SH Additional)
11069001 Atellica Sample Handler (SH Prime)
11069018 Atellica Sample Handler Connect (SHC)
11069400 Atellica Decapper

Name of Manufacturer

Legal Manufacturer

Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown, NY
USA 10591

Manufacturing Site

SIEMENS HEALTHCARE DIAGNOSTICS INC.
500 GBC DR, PO Box 6101
NEWARK, DE
USA 19714

Name of Product(s)

11098500 Atellica IM Acid and IM Base
11417929 Atellica IM Acid
11417930 Atellica IM Base
11098502 Atellica IM Cleaner
11098501 Atellica IM Wash

Name of Manufacturer

Legal Manufacturer

Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown, NY
USA 10591

Manufacturing Site

AXIS-SHIELD DIAGNOSTICS, LTD.





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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 6

LUNA PLACE
THE TECHNOLOGY PARK
DUNDEE, Scotland
UNITED KINGDOM DD2 1XA

Name of Product(s)

10733001 Atellica IM Active-B12 (AB12)
10733002 Atellica IM Active-B12 (AB12) Quality Control
10733003 Atellica IM Active-B12 (AB12) Master Curve Material
10732998 Atellica IM Anti-CCP (aCCP)
10732999 Atellica IM Anti-CCP (aCCP) Quality Control
10733000 Atellica IM Anti-CCP (aCCP) Master Curve Material
10733006 Atellica IM Erythropoietin (EPO)
10733008 Atellica IM Erythropoietin Quality Control Material(EPO QC)
10733004 Atellica IM Calcitonin (Calct)
10733005 Atellica IM Calcitonin Master Curve Material (Calct MCM)

Name of Manufacturer

Legal Manufacturer

Siemens Healthcare Diagnostics Inc.
511 Benedict Ave
Tarrytown, NY
USA 10591

Manufacturing Site

Siemens Healthcare Diagnostics Inc.
333 Coney Street
E Walpole, MA
USA 02032

Name of Product(s)

10995443 Atellica IM AFP MCM (master curve material)
10995441 Atellica IM Alpha Fetoprotein (AFP)
10995442 Atellica IM Alpha Fetoprotein (AFP)
10995458 Atellica IM Ancillary Probe Wash 1 (APW1)
10998580 Atellica IM Ancillary Probe Wash 3 (APW3)
11200558 Atellica IM Androstenedione (ANDRO)
11200557 Atellica IM Androstenedione Master Curve Material (ANDRO MCM)
10995597 Atellica IM Anti-Hepatitis B core Total (HBcT)
10995598 Atellica IM Anti-Hepatitis B core Total Quality Control (HBcT QC)
10995453 Atellica IM Anti-Hepatitis B surface Antigen 2 (aHBs2)
10995667 Atellica IM Anti-Hepatitis B surface Antigen 2 Master Curve Material (aHBs2 MCM)
10995454 Atellica IM Anti-Hepatitis B surface Antigen 2 Quality Control (aHBs2 QC)
10995462 Atellica IM Anti-Thyroglobulin (aTG)
10995461 Atellica IM Anti-Thyroglobulin (aTG)
10995463 Atellica IM Anti-Thyroglobulin Diluent (aTG DIL)
10995464 Atellica IM Anti-Thyroglobulin Master Curve Material (aTG MCM)
10995465 Atellica IM Anti-Thyroglobulin Quality Control (aTG QC)
10995466 Atellica IM Anti-Thyroid Peroxidase (aTPO)
10995467 Atellica IM Anti-Thyroid Peroxidase (aTPO)
10995468 Atellica IM Anti-Thyroid Peroxidase Diluent (aTPO DIL)
10995469 Atellica IM Anti-Thyroid Peroxidase Master Curve Material (aTPO MCM)
10995470 Atellica IM Anti-Thyroid Peroxidase Quality Control (aTPO QC)
10995477 Atellica IM BR 27.29 (BR)
10995478 Atellica IM BR 27.29 (BR)
10995515 Atellica IM BR 27.29 Calibrator (BR CAL)
10995479 Atellica IM BR 27.29 Master Curve Material (BR MCM)
10995480 Atellica IM BR 27.29 Pretreatment Reagent (BR PRE)





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Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 6

11202699 Atellica IM BRAHMS Procalcitonin (PCT)
11202700 Atellica IM BRAHMS Procalcitonin Quality Control (PCT QC)
10998265 Atellica IM BRAHMS Procalcitonin Master Curve Material (PCT MCM)
10995471 Atellica IM B-Type Natriuretic Peptide (BNP)
10995472 Atellica IM B-Type Natriuretic Peptide (BNP)
10995473 Atellica IM B-Type Natriuretic Peptide Calibrator (BNP CAL)
10995474 Atellica IM B-Type Natriuretic Peptide Master Curve Material (BNP MCM)
10995475 Atellica IM B-Type Natriuretic Peptide Quality Control (BNP QC)
10995481 Atellica IM CA 125II (CA 125II)
10995482 Atellica IM CA 125II (CA 125II)
10995483 Atellica IM CA 125II Calibrator (CA 125II CAL)
10995484 Atellica IM CA 125II Master Curve Material (CA 125II MCM)
10995485 Atellica IM CA 15-3 (CA 15-3)
10995486 Atellica IM CA 15-3 (CA 15-3)
10995487 Atellica IM CA 15-3 Calibrator (CA 15-3 CAL)
10995488 Atellica IM CA 15-3 Master Curve Material (CA 15-3 MCM)
10995489 Atellica IM CA 19-9 (CA 19-9)
10995490 Atellica IM CA 19-9 (CA 19-9)
10995491 Atellica IM CA 19-9 Diluent (CA 19-9 DIL)
10995492 Atellica IM CA 19-9 Master Curve Material (CA 19-9 MCM)
10995493 Atellica IM Calibrator 1 (CAL 1)
10995495 Atellica IM Calibrator 30 (CAL 30)
10995496 Atellica IM Calibrator 30 (CAL 30)
10995497 Atellica IM Calibrator 80 (CAL 80)
10995500 Atellica IM Calibrator A (CAL A)
10995501 Atellica IM Calibrator A (CAL A)
10995503 Atellica IM Calibrator B (CAL B)
10995504 Atellica IM Calibrator B (CAL B)
10995506 Atellica IM Calibrator C (CAL C)
10995507 Atellica IM Calibrator C (CAL C)
10995509 Atellica IM Calibrator D (CAL D)
10995510 Atellica IM Calibrator D (CAL D)
10995512 Atellica IM Calibrator E (CAL E)
10995513 Atellica IM Calibrator E (CAL E)
10995516 Atellica IM Calibrator O (CAL O)
10995517 Atellica IM Calibrator Q (CAL Q)
10995518 Atellica IM Calibrator Q (CAL Q)
10995519 Atellica IM Calibrator U (CAL U)
10995520 Atellica IM Calibrator Y (CAL Y)
10995521 Atellica IM Calibrator Z (CAL Z)
10995523 Atellica IM Carcinoembryonic Antigen (CEA)
10995524 Atellica IM Carcinoembryonic Antigen (CEA)
10995525 Atellica IM Carcinoembryonic Diluent (CEA DIL)
10995526 Atellica IM Carcinoembryonic Master Curve Material (CEA MCM)
10995544 Atellica IM Complexed ProstateSpecific Antigen (cPSA)
10995537 Atellica IM Cortisol (Cor)
10995538 Atellica IM Cortisol (Cor)
10995539 Atellica IM Cortisol Master Curve Material (Cor MCM)
10995540 Atellica IM Cortisol Urine Reconstitution Buffer
10995545 Atellica IM cPSA MCM (master curve material)
10995546 Atellica IM cPSA Pretreatment Reagent (cPSA PRE)
10995547 Atellica IM cPSA QC (quality control material)
10995530 Atellica IM Creatine Kinase MB (CKMB)
10995531 Atellica IM Creatine Kinase MB (CKMB)
10995532 Atellica IM Creatine Kinase MB Calibrator (CKMB CAL)
10995533 Atellica IM Creatine Kinase MB Diluent (CKMB DIL)
10995534 Atellica IM Creatine Kinase MB Master Curve Material (CKMB MCM)
10995552 Atellica IM CsA Pretreatment Reagent (CsA PRE)





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10995548 Atellica IM Cyclosporine (CsA)
10995549 Atellica IM Cyclosporine Calibrator (CsA CAL)
10995551 Atellica IM Cyclosporine Master Curve Material (CsA MCM)
11202207 Atellica IM Cytomegalovirus IgG (CMVG)
11202209 Atellica IM CMV IgG Quality Control (CMVG IgG QC)
10995555 Atellica IM DHEA-SO4 (DHEAS)
10995556 Atellica IM DHEA-SO4 Master Curve Material (DHEAS MCM)
10995553 Atellica IM Digitoxin (Dgtn)
10995554 Atellica IM Digitoxin (Dgtn)
10995557 Atellica IM Digoxin (Dig)
10995558 Atellica IM Digoxin (Dig)
10995559 Atellica IM Digoxin Master Curve Material (Dig MCM)
10995561 Atellica IM Enhanced Estradiol (eE2)
10995562 Atellica IM Enhanced Estradiol (eE2)
10995563 Atellica IM Enhanced Estradiol Diluent (eE2 DIL)
10995564 Atellica IM Enhanced Estradiol Master Curve Material (eE2 MCM)
10995568 Atellica IM Ferritin (Fer)
10995569 Atellica IM Ferritin (Fer)
10995570 Atellica IM Ferritin Master Curve Material (Fer MCM)
10995572 Atellica IM Folate (Fol)
10995573 Atellica IM Folate (Fol)
10995574 Atellica IM Folate Diluent (Fol DIL)
10995576 Atellica IM Folate DTT/Releasing Agent (Fol DTT / REL):
- Atellica IM Folate DTT Reagent (Fol DTT) - Atellica IM Folate Releasing Agent (Fol REL)
10995575 Atellica IM Folate Master Curve Material (Fol MCM)
10995580 Atellica IM Follicle Stimulating Hormone (FSH)
10995581 Atellica IM Follicle Stimulating Hormone (FSH)
10995582 Atellica IM Follicle Stimulating Hormone Master Curve Material (FSH MCM)
10995588 Atellica IM Free Thyroxine (FT4)
10995589 Atellica IM Free Thyroxine (FT4)
10995590 Atellica IM Free Thyroxine Master Curve Material (FT4 MCM)
10995584 Atellica IM Free Triiodothyronine (FT3)
10995585 Atellica IM Free Triiodothyronine (FT3)
10995586 Atellica IM Free Triiodothyronine Master Curve Material (FT3 MCM)
10995444 Atellica IM Hepatitis A IgM (aHAVM)
10995445 Atellica IM Hepatitis A IgM Quality Control (aHAVM QC)
10995446 Atellica IM Hepatitis A Total (aHAVT)
10995448 Atellica IM Hepatitis A Total Quality Control (aHAVT QC)
10995449 Atellica IM Hepatitis B core Antigen (aHBcM)
10995450 Atellica IM Hepatitis B Core Antigen Quality Control (aHBcM QC)
10995600 Atellica IM Hepatitis B e Antigen (HBeAg)
10995601 Atellica IM Hepatitis B e Antigen Quality Control (HBeAg QC)
10995604 Atellica IM Hepatitis B surface Antigen II (HBsII)
10995603 Atellica IM Hepatitis B surface Antigen II Confirmatory (HBsII Conf)
10995605 Atellica IM Hepatitis B surface Antigen II Quality Control (HBsII QC)
10995456 Atellica IM Hepatitis C (aHCV)
10995457 Atellica IM Hepatitis C Quality Control (aHCV QC)
10995591 Atellica IM HER-2/neu (H2n)
10995592 Atellica IM HER-2/neu Calibrator (H2n CAL)
10995593 Atellica IM HER-2/neu Master Curve Material (H2n MCM)
10995594 Atellica IM HER-2/neu Quality Control (H2n QC)
10997840 Atellica IM High Sensitivity Troponin I (TnIH)
10997841 Atellica IM High Sensitivity Troponin I (TnIH)
10997842 Atellica IM High Sensitivity Troponin I Master Curve Material (TnIH MCM)
10995606 Atellica IM Homocysteine (HCY)
10995607 Atellica IM Homocysteine (HCY)
10995498 Atellica IM Homocysteine Calibrator (HCY CAL)
10995608 Atellica IM Homocysteine Diluent (HCY DIL)





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10995609 Atellica IM Homocysteine Master Curve Material (HCY MCM)
10995621 Atellica IM Intact Parathyroid Hormone (PTH)
10995622 Atellica IM Intact Parathyroid Hormone (PTH)
10995625 Atellica IM Intact Parathyroid Hormone Master Curve Material (PTH MCM)
10995626 Atellica IM Intact Parathyroid Hormone Quality Control (PTH QC)
10995634 Atellica IM Luteinizing Hormone (LH)
10995635 Atellica IM Luteinizing Hormone (LH)
10995636 Atellica IM Luteinizing Hormone Master Curve Material (LH MCM)
10995639 Atellica IM Multi-Diluent 1
10995637 Atellica IM Multi-Diluent 1
10995638 Atellica IM Multi-Diluent 1
10995640 Atellica IM Multi-Diluent 10
10995642 Atellica IM Multi-Diluent 11
10995641 Atellica IM Multi-Diluent 11
10995550 Atellica IM Multi-Diluent 12
10995643 Atellica IM Multi-Diluent 13
11200798 Atellica IM Multi-Diluent 15
10995644 Atellica IM Multi-Diluent 2
10995645 Atellica IM Multi-Diluent 3
10995647 Atellica IM Multi-Diluent 5
10995648 Atellica IM Myoglobin (MYO)
10995649 Atellica IM Myoglobin (MYO)
10995650 Atellica IM Myoglobin Master Curve Material (MYO MCM)
10995666 Atellica IM Probe Wash 3 (PW3)
10995659 Atellica IM Progesterone (PRGE)
10995660 Atellica IM Progesterone (PRGE)
10995661 Atellica IM Progesterone Master Curve Material (PRGE MCM)
10995655 Atellica IM Prolactin (PRL)
10995656 Atellica IM Prolactin (PRL)
10995657 Atellica IM Prolactin Master Curve Material (PRL MCM)
10995662 Atellica IM Prostate Specific Antigen (PSA)
10995663 Atellica IM Prostate Specific Antigen (PSA)
10995664 Atellica IM Prostate-Specific Antigen Master Curve Material (PSA MCM)
10995440 Atellica IM RBC Folate Ascorbic Acid/ Ascorbic Acid Diluent (RBC FOL)
10995670 Atellica IM Rubella IgG (Rub G)
10995671 Atellica IM Rubella IgG Quality Control (Rub G QC)
10995668 Atellica IM Rubella IgM (Rub M)
10995669 Atellica IM Rubella IgM Quality Control (Rub M QC)
10995672 Atellica IM Sex Hormone Binding Globulin (SHBG)
10995673 Atellica IM Sex Hormone Binding Globulin Calibrator (SHBG CAL)
10995674 Atellica IM Sex Hormone Binding Globulin Master Curve Material (SHBG MCM)
10995675 Atellica IM Syphilis (Syph)
10995676 Atellica IM Syphilis Quality Control (Syph QC)
10995682 Atellica IM T3/T4/VB12 Ancillary Reagent (T3/T4/VB12 ANC)
10995683 Atellica IM T3/T4/VB12 Ancillary Reagent (T3/T4/VB12 ANC)
10995707 Atellica IM Testosterone II (TSTII)
10995708 Atellica IM Testosterone II (TSTII)
10995709 Atellica IM Testosterone II Master Curve Material (TSTII MCM)
10995705 Atellica IM Thyroid Stimulating Hormone 3 Ultra Master Curve Material (TSH3-UL MCM)
10995703 Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)
10995704 Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)
10995711 Atellica IM Thyroid Uptake (TUp)
10995712 Atellica IM Thyroid Uptake (TUp)
10995689 Atellica IM Total hCG (ThCG)
10995690 Atellica IM Total hCG (ThCG)
10995691 Atellica IM Total hCG Diluent (ThCG DIL)
10995692 Atellica IM Total hCG Diluent (ThCG DIL)
10995693 Atellica IM Total hCG Diluent (ThCG DIL)





Certificate No. 218-10-2023

Certificate to Foreign Government - Name of Product(s) Attachment Page 6 of 6

- 10995694 Atellica IM Total hCG Master Curve Material (ThCG MCM)
 - 10995614 Atellica IM Total IgE (tIgE)
 - 10995615 Atellica IM Total IgE (tIgE)
 - 10995616 Atellica IM Total IgE Diluent (tIgE DIL)
 - 10995617 Atellica IM Total IgE Master Curve Material (tIgE MCM)
 - 10995684 Atellica IM Total Thyroxine (T4)
 - 10995685 Atellica IM Total Thyroxine (T4)
 - 10995686 Atellica IM Total Thyroxine Diluent (T4 DIL)
 - 10995687 Atellica IM Total Thyroxine Master Curve Material (T4 MCM)
 - 10995678 Atellica IM Total Triiodothyronine (T3)
 - 10995679 Atellica IM Total Triiodothyronine (T3)
 - 10995680 Atellica IM Total Triiodothyronine Diluent (T3 DIL)
 - 10995681 Atellica IM Total Triiodothyronine Master Curve Material (T3 MCM)
 - 10995699 Atellica IM Toxoplasma IgG (Toxo G)
 - 10995700 Atellica IM Toxoplasma IgG Quality Control (Toxo G QC)
 - 10995701 Atellica IM Toxoplasma IgM (Toxo M)
 - 10995702 Atellica IM Toxoplasma IgM Quality Control (Toxo M QC)
 - 10995696 Atellica IM Troponin I Ultra (TnlUltra)
 - 10995697 Atellica IM Troponin I Ultra (TnlUltra)
 - 10995698 Atellica IM Troponin I Ultra Master Curve Material (Tnl-Ultra MCM)
 - 10995714 Atellica IM Vitamin B12 (VB12)
 - 10995715 Atellica IM Vitamin B12 (VB12)
 - 10995716 Atellica IM Vitamin B12 Diluent (VB12 DIL)
 - 10995718 Atellica IM Vitamin B12 DTT/Releasing Agent (VB12 DTT/REL)
 - 10995717 Atellica IM Vitamin B12 Master Curve Material (VB12 MCM)
 - 10995719 Atellica IM Vitamin D Total (VitD)
 - 10995720 Atellica IM Vitamin D Total (VitD)
 - 10995721 Atellica IM Vitamin D Total Diluent (VitD DIL)
 - 10995723 Atellica IM Vitamin D Total Master Curve Material (VitD MCM)
 - 10995724 Atellica IM Vitamin D Total Quality Control (VitD QC)
- END OF PRODUCT LIST-----



ChamberNet

A local Chamber of Commerce

Official Certification

Serial Number: **3839281**

Based solely upon information supplied, ChamberNet, a nationally recognized chamber of commerce, hereby declares to the best of its knowledge and belief, that the the U.S. Food & Drug certificate number 218-10-2026 Issued for Siemens Healthcare Diagnostics Inc. , for use in Vietnam has been examined and found to be original . The authenticity of the seal or stamp of the the issuer Cesar A. Perez , hereunto annexed, whose term of office included the date of October 10, 2023 This attestation does not certify the content of the document for which it was issued.

In testimony whereof, I have hereunto set my hand and affixed the great seal of ChamberNet, located in Washington DC on this 19th day of March 2024.



Dolly Porzillo

Washington branch manager

ChamberNet
— Local Chamber of Commerce —

To verify the authenticity of this declaration, please visit www.chambernet.com and enter the serial number.

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