

# EC Certificate



**Full Quality Assurance System**  
**Directive 98/79/EC on In Vitro Diagnostic Medical Devices,**  
**Annex IV excluding (4, 6)**

Registration No.: HL 1290554-1

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

Products: List B Products included:

- ADVIA Centaur® Free PSA (fPSA) SMN-10283414 Ref-06862518
- VERSANT CT/GC DNA 1.0 Assay (kPCR)  
SMN-10286028 Ref-04801693
- ADVIA Centaur® Rubella G (Rub G) SMN-10310283 Ref-08666235
- ADVIA Centaur® Rub G Quality Control Material  
SMN-10310284 Ref-01549403
- ADVIA Centaur® Rubella M (Rub M) SMN-10310285 Ref-02633319
- ADVIA Centaur® Rub M Quality Control Material  
SMN-10310286 Ref-00347629
- ADVIA Centaur® PSA SMN-10310292 Ref-06574155
- ADVIA Centaur® PSA SMN-10310293 Ref-02676506
- ADVIA Centaur® Calibrator Q SMN-10310295 Ref-02484801
- ADVIA Centaur® Calibrator Q SMN-10310296 Ref-04847308

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1111761-10

Effective date: 2022-05-23

Expiry date: 2024-12-03

Issue date: 2022-05-23



Katja Mierisch  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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Manufacturer: Siemens Healthcare Diagnostics Inc.  
511 Benedict Ave  
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- ADVIA Centaur® Toxoplasma M SMN-10310320 Ref-05303018
- ADVIA Centaur® Toxoplasma G (Toxo G)  
SMN-10310321 Ref-04520287
- ADVIA Centaur® Toxo G Quality Control Material  
SMN-10310325 Ref-06317233
- ADVIA Centaur® Toxo M Quality Control Material  
SMN-10310326 Ref-03089388
- ADVIA Centaur® cPSA SMN-10310381 Ref-06684007
- ADVIA Centaur® Calibrator Y SMN-10310383 Ref-02614268
- ADVIA Centaur® cPSA Pretreatment Reagent  
SMN-10310384 Ref-09702804
- ADVIA Centaur® cPSA 1,2,3 Quality Control Material  
SMN-10310387 Ref-02508026
- ADVIA Centaur® fPSA Calibrator SMN-10361919 Ref-04846115
- ADVIA Centaur® Rubella G II (RbGII) Quality Control SMN-10377512
- ADVIA Centaur® Rubella G II (RbGII) SMN-10377513
- ADVIA Centaur® CMV IgG (CMV IgG) SMN-10630612
- ADVIA Centaur® CMV IgG (CMV IgG) Quality Control SMN-10630613
- ADVIA Centaur® CMV IgM (CMV IgM) SMN-10630614
- ADVIA Centaur® CMV IgM (CMV IgM QC) Quality Control  
SMN-10630615

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A blue ink signature is written over a circular blue stamp. The stamp contains the TÜVRheinland logo and the text 'TÜVRheinland LGA Products GmbH' and 'Zertifizierungsstelle'.

Katja Mierisch  
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- ADVIA Centaur® Rubella G II (RbGII) Master Curve Material  
SMN-10698772
- Atellica® IM Free Beta Human Chorionic Gonadotropin (FBHCG)  
SMN-10733009
- Atellica® IM Free Beta Human Chorionic Gonadotropin (FBHCG)  
SMN-10733010
- ADVIA Centaur® Free Beta Human Chorionic Gonadotropin (FBHCG)  
SMN-10994996
- ADVIA Centaur® Free Beta Human Chorionic Gonadotropin (FBHCG)  
SMN-10994997
- ADVIA Centaur® Pregnancy-Associated Plasma Protein-A (PAPP-A)  
SMN-10995000
- ADVIA Centaur® Pregnancy-Associated Plasma Protein-A (PAPP-A)  
SMN-10995001
  
- Atellica® IM Pregnancy-Associated Plasma Protein-A (PAPP-A)  
SMN-10733019
- Atellica® IM Pregnancy-Associated Plasma Protein-A (PAPP-A)  
SMN-10733020
- Atellica® IM Calibrator Q (CAL Q) SMN-10995517
- Atellica® IM Calibrator Q (CAL Q) SMN-10995518
- Atellica® IM Calibrator Y (CAL Y) SMN-10995520

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511 Benedict Ave  
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- Atellica® IM Complexed Prostate-Specific Antigen (cPSA) SMN-10995544
- Atellica® IM cPSA PRE SMN-10995546
- Atellica® IM Complexed Prostate-Specific Antigen Quality Control (cPSA QC) SMN-10995547
- Atellica® IM Free Prostate-Specific Antigen (fPSA) SMN-10995577
- Atellica® IM Free Prostate-Specific Antigen Calibrator (fPSA CAL) SMN-10995578
- Atellica® IM Prostate-Specific Antigen (PSA) SMN-10995662
- Atellica® IM Prostate-Specific Antigen (PSA) SMN-10995663
- Atellica® IM Rubella G II Master Curve Material (RbGII MCM) SMN-11203585
- Atellica® IM Rubella G II (RbGII) SMN-11203564
- Atellica® IM Rubella G II Quality Control (RbGII QC) SMN-11203576
- Atellica® IM Rubella IgM (Rub M) SMN-10995668
- Atellica® IM Rubella IgM Quality Control (Rub M QC) SMN-10995669
- Atellica® IM Rubella IgG (Rub G) SMN-10995670
- Atellica® IM Rubella IgG Quality Control (Rub G QC) SMN-10995671
- Atellica® IM Toxoplasma IgG (Toxo G) SMN-10995699
- Atellica® IM Toxoplasma IgG Quality Control (Toxo G QC) SMN-10995700
- Atellica® IM Toxoplasma IgM (Toxo M) SMN-10995701

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511 Benedict Ave  
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- Atellica® IM Toxoplasma IgM Quality Control (Toxo M QC) SMN-10995702
- Atellica® IM CMV IgG (CMV IgG) SMN-11202207
- Atellica® IM CMV IgG Quality Control (CMV IgG QC) SMN-11202209
- Atellica® IM CMV IgM (CMV IgM) SMN-11202488
- Atellica® IM CMV IgM (CMV IgM QC) Quality Control SMN-11202489

List A Products included:

- ADVIA Centaur® Hepatitis B e Antigen (HBeAg) SMN-10291295 Ref-0152127
- ADVIA Centaur® HBeAg Quality Control Material SMN-10291296 Ref-01512437
- Atellica® IM Hepatitis B e Antigen (HBeAg) SMN-10995600
- Atellica® IM Hepatitis B e Antigen Quality Control (HBeAg QC) SMN-10995601
  
- ADVIA Centaur® HBc IgM (aHBcM) SMN-10308978 Ref-00504619
- ADVIA Centaur® HBc IgM Quality Control Material SMN-10308979 Ref-00504945
- Atellica® IM Hepatitis B Core Antigen (aHBcM) SMN-10995449

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- Atellica® IM Hepatitis B Core Antigen Quality Control (aHBcM QC)  
SMN-10995450
- ADVIA Centaur® EHIV Quality Control Material  
SMN-10309010 Ref-01324827
- ADVIA Centaur® HIV 1/O/2 Enhanced (EHIV)  
SMN-10309022 Ref-01463908
- Atellica® IM HIV 1/O/2 Enhanced (EHIV) SMN-10995610
- Atellica® IM HIV 1/O/2 Enhanced Quality Control (EHIV QC)  
SMN-10995612
- ADVIA Centaur® HBsAg Confirmatory (Conf)  
SMN-10309058 Ref-03393818
- Atellica® IM Hepatitis B surface Antigen II Confirmatory (HBsII Conf)  
SMN-10995603
- ADVIA Centaur® HBsAg Quality Control Material SMN-10309059
- ADVIA Centaur® HBsAgII (HBsII) SMN-10492138
- ADVIA Centaur® HBsAgII (HBsII) (for use on the Centaur CP)  
SMN-10994742

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- Atellica® IM Hepatitis B surface Antigen II (HBsII) SMN-10995604
- Atellica® IM Hepatitis B surface Antigen II Quality Control (HBsII QC) SMN-10995605
- ADVIA Centaur® HCV (aHCV) SMN-10309061 Ref-03438099
- ADVIA Centaur® HCV Quality Control Material SMN-10309062 Ref-03439141
- Atellica® IM Hepatitis C (aHCV) SMN-10995456
- Atellica® IM Hepatitis C Quality Control (aHCV QC) SMN-10995457
  
- ADVIA Centaur® HBc Total (HBcT) SMN-10309508 Ref-07566733
- ADVIA Centaur® HBcT Quality Control Material SMN-10309509 Ref-07569996
- Atellica® IM Anti-Hepatitis B core Total (HBcT) SMN-10995597
- Atellica® IM Anti-Hepatitis B core Total Quality Control SMN-10995598
  
- ADVIA Centaur® Anti-HBe (aHBe) SMN-10334094 Ref-03150214
- ADVIA Centaur® anti-HBe Quality Control SMN-10334181 Ref-03221634
- Atellica® IM Anti-Hepatitis B e Antigen (aHBe) SMN-10995451
- Atellica® IM Anti-Hepatitis B e Antigen Quality Control (aHBe QC) SMN-10995452

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- ADVIA Centaur® HIV Ag/Ab Combo (CHIV)  
SMN-10283020 Ref-06520528
- ADVIA Centaur® CHIV Quality Control Material  
SMN-10283022 Ref-06520544
- Atellica® IM HIV Ag/Ab Combo (CHIV) SMN-10995527
- Atellica® IM HIV Ag/Ab Combo Quality Control (CHIV QC)  
SMN-11200769
  
- ADVIA Centaur® Anti-HBs2 (aHBs2) SMN-10286268 Ref-04670661
- ADVIA Centaur® Anti-HBs2 Quality Control Material  
SMN-10283088 Ref-06521435
- Atellica® IM Anti-Hepatitis B surface Antigen 2 (aHBs2) SMN-10995453
- Atellica® IM Anti-Hepatitis B surface Antigen 2 Quality Control (aHBs2  
QC) SMN-10995454
  
- ADVIA Centaur® anti-HBe2 (aHBe2) SMN- 10720831
- ADVIA Centaur® anti-HBe2 (aHBe2) Quality Control SMN- 10720832
- Atellica® IM anti-HBe2 (aHBe2) SMN- 107233021
- Atellica® IM anti-HBe2 (aHBe2) Quality Control SMN- 107330222

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- VERSANT HCV Amplification 2.0 Kit (LiPA)  
SMN-10325050 Ref-06718688
- VERSANT HCV Control 2.0 Kit (LiPA) SMN-10325051 Ref-06719269
- VERSANT HCV Genotype 2.0 Assay (LiPA)  
SMN-10325052 Ref-06719382
  
- VERSANT HCV RNA 1.0 Assay (kPCR) 1 of 2 SMN-10469013
- VERSANT HCV RNA 1.0 Assay (kPCR) 2 of 2 SMN-10469014
- VERSANT HIV-1 RNA 1.5 Assay (kPCR) 1 of 2 SMN-10729727
- VERSANT HIV-1 RNA 1.5 Assay (kPCR) 2 of 2 SMN-10729728
- VERSANT HBV DNA 1.0 Assay (kPCR) 1 of 2  
SMN-10282480 Ref-06497151
- VERSANT HBV DNA 1.0 Assay (kPCR) 2 of 2  
SMN-10282481 Ref-06497178

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## Self-Test Products included:

- Hemastix® SMN-10314716 Ref-01152317
- Hemastix® Reagent Strips SMN-10317353 Ref-02597428
- Hemastix® Reagent Strips SMN-10324683 Ref-06546712
- Albustix® Reagent Strips SMN-10317384 Ref-02614217
- Albustix® Reagent Strips SMN-10318774 Ref-03348227
- Albustix® Reagent Strips SMN-10323903 Ref-06184853
- CLINITEK® Microalbumin 2 SMN-10318739 Ref-03330964
- CLINITEK® Microalbumin 9 Reagent Strips SMN-10285741  
Ref-06916863
- CLINITEK Status®+ Analyzer SMN-11317309
- CLINITEK Status®+ Analyzer SMN-11317310
- CLINITEK Status®+ Analyzer SMN-11317311
- CLINITEK Status®+ Analyzer SMN-11317312
- CLINITEK Status®+ Analyzer SMN-11317313
- CLINITEK Status®+ Analyzer SMN-11317314
- Multistix® GP SMN-10321054 Ref-04624902
- Multistix® 5 SMN-10326466 Ref-07500392
- Multistix® 7 SMN-10314818 Ref-01211267
- Multistix® 10SG SMN-10315394 Ref-01526748
- Multistix® 10SG SMN-10319565 Ref-03783489

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- Multistix® 10SG SMN-10322360 Ref-05328339
- Multistix® 8SG SMN-10320335 Ref-04200746
- Multistix® 8SG SMN-10322217 Ref-05258055
  
- Uritest® SMN-10328167 Ref-08408406
- Uritest® 2 SMN-10326704 Ref-07639781
  
- DCA Vantage® Analyzer SMN-10845062
- DCA® Systems Hemoglobin A1c Reagent Kit SMN-10888639

Replaces Certificate, Registration No.: HL 60145038 0001

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Tarrytown NY 10591  
USA

The scope of certification includes the following manufacturing sites:

No.	Location	Scopes
/01	Siemens Healthcare Diagnostics Inc. 511 Benedict Ave Tarrytown NY 10591 USA	Design and development, manufacture
/02	Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole MA 02032 USA	Manufacture
/03	Siemens Healthcare Diagnostics Manufacturing Ltd Northern Road Chilton Industrial Estate Sudbury Suffolk CO10 2XQ United Kingdom	Manufacture

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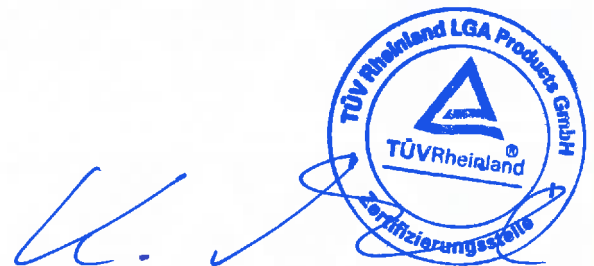
Registration No.: HL 1290554-1

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

The scope of certification includes the following manufacturing sites:

- |     |   |                        |
|-----|---|------------------------|
| /04 | Siemens Healthcare Diagnostics Inc.<br>430 South Beiger Street<br>Mishawaka IN 46544<br>USA | Manufacture            |
| /05 | Siemens Healthcare Diagnostics Inc.<br>02 Edgewater Drive<br>Norwood MA 02062<br>USA        | Design and development |
| /06 | Siemens Healthcare Diagnostics Inc.<br>3400 Middlebury Street<br>Elkhart IN 46516<br>USA    | Design and development |

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