

EU Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY, 10591-5097, USA
Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur HBsAgII
Catalogue Number (REF):	10492138 (ADVIA Centaur) 10994742 (ADVIA Centaur CP)
Siemens Material Number (SMN):	10492138 (ADVIA Centaur) 10994742 (ADVIA Centaur CP)
Legacy Product Code:	N/A
Classification:	ANNEX II, List A
Conformity Assessment Route:	ANNEX IV
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
Document Identifier:	DoC_ADVIA Centaur HBsII
Version:	4.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
[YYYY-MM-DD]

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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur T3
Catalogue Number (REF):	04779671 (1-pack) 04779663 (5-pack)
Siemens Material Number (SMN):	10285733 (1-pack) 10285732 (5-pack)
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur T3
Version:	2.0

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333 Coney Street
East Walpole, MA, 02032, USA

EU Authorized Representative: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name: ADVIA Centaur HCV

Catalogue Number (REF): 03438099

Siemens Material Number (SMN): 10309061

Legacy Product Code: N/A

Classification: ANNEX II, List A

Conformity Assessment Route: ANNEX IV

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nuremberg, Germany
Identification No. 0197

Document Identifier: DoC_ADVIA Centaur HCV

Version: 4.0

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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur T4
Catalogue Number (REF):	08074354 (1-pack) 09236439 (5-pack)
Siemens Material Number (SMN):	10309960 (1-pack) 10309961 (5-pack)
Legacy Product Code:	110735 (1-pack) 110736 (5-pack)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur T4
Version:	2.0

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EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur TSH3-Ultra
Catalogue Number (REF):	06491072 (1-pack) 06491080 (5-pack)
Siemens Material Number (SMN):	10282378 (1-pack) 10282379 (5-pack)
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_ADVIA Centaur TSH3-UL
Version:	3.0

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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur FT4
Catalogue Number (REF):	06490092 (1-pack) 06490106 (5-pack)
Siemens Material Number (SMN):	10282218 (1-pack) 10282219 (5-pack)
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur FT4
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EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Testosterone II
Catalogue Number (REF):	10696862 (1-pack) 10696863 (5-pack)
Siemens Material Number (SMN):	10696862 (1-pack) 10696863 (5-pack)
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_ADVIA Centaur TSTII
Version:	2.0

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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur anti-TPO
Catalogue Number (REF):	10630886 (1-pack) 10630887 (5-pack)
Siemens Material Number (SMN):	10630886 (1-pack) 10630887 (5-pack)
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur aTPO
Version:	2.0

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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Prolactin
Catalogue Number (REF):	03278474 (1-pack) 09505871 (5-pack)
Siemens Material Number (SMN):	10309975 (1-pack) 10309976 (5-pack)
Legacy Product Code:	110757 (1-pack) 110758 (5-pack)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur PRL
Version:	2.0

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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Total IgE
Catalogue Number (REF):	06843687 (1-pack) 03359776 (5-pack)
Siemens Material Number (SMN):	10309985 (1-pack) 10309986 (5-pack)
Legacy Product Code:	110777 (1-pack) 110778 (5-pack)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur tIgE
Version:	2.0

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EU Authorized Representative: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name: ADVIA Centaur Free PSA

Catalogue Number (REF): 06862518

Siemens Material Number (SMN): 10283414

Legacy Product Code: N/A

Classification: ANNEX II, List B

Conformity Assessment Route: ANNEX IV

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nuremberg, Germany
Identification No. 0197

Document Identifier: DoC_ADVIA Centaur fPSA

Version: 4.0

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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur CA 125II
Catalogue Number (REF):	09427226 (1-pack) 01678114 (5-pack)
Siemens Material Number (SMN):	10310443 (1-pack) 10315696 (5-pack)
Legacy Product Code:	128532 (1-pack) 128533 (5-pack)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur CA 125II
Version:	2.0

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East Walpole, MA, 02032, USA

EU Authorized Representative: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name: ADVIA Centaur HBc Total Quality Control Material

Catalogue Number (REF): 07569996

Siemens Material Number (SMN): 10309509

Legacy Product Code: N/A

Classification: ANNEX II, List A

Conformity Assessment Route: ANNEX IV

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nuremberg, Germany
Identification No. 0197

Document Identifier: DoC_ADVIA Centaur HBcT QC

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EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Anti-HBs2 Quality Control Material
Catalogue Number (REF):	06521435
Siemens Material Number (SMN):	10283088
Legacy Product Code:	N/A
Classification:	ANNEX II, List A
Conformity Assessment Route:	ANNEX IV
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
Document Identifier:	DoC_ADVIA Centaur aHBs2 QC
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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur AFP
Catalogue Number (REF):	03974780 (1-pack) 03305838 (5-pack)
Siemens Material Number (SMN):	10309979 (1-pack) 10309980 (5-pack)
Legacy Product Code:	110763 (1-pack) 110764 (5-pack)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur AFP
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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur CEA
Catalogue Number (REF):	00937450 (1-pack) 09788458 (5-pack)
Siemens Material Number (SMN):	10309977 (1-pack) 10309978 (5-pack)
Legacy Product Code:	110761 (1-pack) 110762 (5-pack)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur CA 19-9
Catalogue Number (REF):	10491379 (1-pack) 10491244 (5-pack)
Siemens Material Number (SMN):	10491379 (1-pack) 10491244 (5-pack)
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur CA 19-9
Version:	2.0

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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur CA 15-3
Catalogue Number (REF):	08126338 (1-pack) 00128609 (5-pack)
Siemens Material Number (SMN):	10327620 (1-pack) 10312831 (5-pack)
Legacy Product Code:	128534 (1-pack) 128535 (5-pack)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur CA 15-3
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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Calibrator A
Catalogue Number (REF):	04800646 (2-pack) 04800735 (6-pack)
Siemens Material Number (SMN):	10285903 (2-pack) 10285904 (6-pack)
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Calibrator B
Catalogue Number (REF):	00649625 (2-pack) 00652707 (6-pack)
Siemens Material Number (SMN):	10308986 (2-pack) 10331729 (6-pack)
Legacy Product Code:	N/A
Classification:	General IVD
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EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Calibrator Q
Catalogue Number (REF):	02484801 (2-pack) 04847308 (6-pack)
Siemens Material Number (SMN):	10310295 (2-pack) 10310296 (6-pack)
Legacy Product Code:	118220 (2-pack) 118221 (6-pack)
Classification:	ANNEX II, List B
Conformity Assessment Route:	ANNEX IV
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
Document Identifier:	DoC_ADVIA Centaur Cal Q
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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Calibrator 80
Catalogue Number (REF):	10492491
Siemens Material Number (SMN):	10492491
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur Cal 80
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EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Calibrator O
Catalogue Number (REF):	10630932
Siemens Material Number (SMN):	10630932
Legacy Product Code:	N/A
Classification:	General IVD
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511 Benedict Avenue
Tarrytown, NY, 10591-5097, USA

Place of Manufacture: Siemens Healthcare Diagnostics Inc.
333 Coney Street
East Walpole, MA, 02032, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name: ADVIA Centaur CA 125II Calibrator

Catalogue Number (REF): 09750760

Siemens Material Number (SMN): 10310444

Legacy Product Code: 128536

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ADVIA Centaur CA 125II Cal

Version: 2.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
[YYYY-MM-DD]

EC Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY, 10591-5097, USA
Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA
EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Calibrator D
Catalogue Number (REF):	04956492 (2-pack) 07176714 (6-pack)
Siemens Material Number (SMN):	10311569 (2-pack) 10311576 (6-pack)
Legacy Product Code:	672173 (2-pack) 672183 (6-pack)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur Cal D
Version:	2.0

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Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

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Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA
EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Ancillary Probe Wash 1
Catalogue Number (REF):	03395373
Siemens Material Number (SMN):	10309060
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur APW1
Version:	2.0

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Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
[YYYY-MM-DD]

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Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY, 10591, USA
Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA
EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Ancillary Probe Wash 3
Catalogue Number (REF):	10699211
Siemens Material Number (SMN):	10699211
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur APW3
Version:	2.0

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Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
[YYYY-MM-DD]

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Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY, 10591-5097, USA
Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA
EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur T3/T4/VB12 Ancillary Reagent
Catalogue Number (REF):	03644012 (2-pack) 01514596 (6-pack)
Siemens Material Number (SMN):	10319315 (2-pack) 10309954 (6-pack)
Legacy Product Code:	110328 (2-pack) 110329 (6-pack)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur T3 T4 VB12 Anc
Version:	2.0

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Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

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511 Benedict Avenue
Tarrytown, NY, 10591-5097, USA

Place of Manufacture: Siemens Healthcare Diagnostics Inc.
333 Coney Street
East Walpole, MA, 02032, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name: ADVIA Centaur Probe Wash 3

Catalogue Number (REF): 03333963

Siemens Material Number (SMN): 10334314

Legacy Product Code: N/A

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ADVIA Centaur PW3

Version: 2.0

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Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

EU Declaration of Conformity



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Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY, 10591-5097, USA
Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur HBsAg Quality Control Material
Catalogue Number (REF):	03394660
Siemens Material Number (SMN):	10309059
Legacy Product Code:	N/A
Classification:	ANNEX II, List A
Conformity Assessment Route:	ANNEX IV
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
Document Identifier:	DoC_ADVIA Centaur HBs QC
Version:	4.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
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Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
[YYYY-MM-DD]

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Legal Manufacturer: Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY, 10591-5097, USA

Place of Manufacture: Siemens Healthcare Diagnostics Inc.
333 Coney Street
East Walpole, MA, 02032, USA

EU Authorized Representative: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name: ADVIA Centaur HCV Quality Control Material

Catalogue Number (REF): 03439141

Siemens Material Number (SMN): 10309062

Legacy Product Code: N/A

Classification: ANNEX II, List A

Conformity Assessment Route: ANNEX IV

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nuremberg, Germany
Identification No. 0197

Document Identifier: DoC_ADVIA Centaur HCV QC

Version: 4.0

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Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
[YYYY-MM-DD]

EU Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Inc.
333 Coney Street
East Walpole, MA, 02032, USA

EU Authorized Representative: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name: ADVIA Centaur® HBc Total 2 (HBcT2)

Catalogue Number (REF): 10376698

Siemens Material Number (SMN): 10376698

Classification: ANNEX II, List A

Conformity Assessment Route: ANNEX IV

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nuremberg, Germany
Identification No. 0197

Document Identifier: DoC_ADVIA Centaur HBcT2

Version: 1.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd, UK

2019-08-16

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Anti-HBs2
Catalogue Number (REF):	04670661
Siemens Material Number (SMN):	10286268
Legacy Product Code:	N/A
Classification:	ANNEX II, List A
Conformity Assessment Route:	ANNEX IV
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
Document Identifier:	DoC_ADVIA Centaur aHBs2
Version:	4.0

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Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
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Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA
EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur anti-TPO 1,2 Quality Control Material
Catalogue Number (REF):	10630936
Siemens Material Number (SMN):	10630936
Legacy Product Code:	N/A
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ADVIA Centaur aTPO QC
Version:	2.0

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Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
[YYYY-MM-DD]

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Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY, 10591, USA
Place of Manufacture:	Fisher Diagnostics A division of Fisher Scientific Company, LLC A part of Thermo Fisher Scientific, Inc. 8365 Valley Pike Middletown, VA, 22645, USA
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Cleaning Solution Concentrate
Catalogue Number (REF):	09908593
Siemens Material Number (SMN):	10310041
Legacy Product Code:	112748
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_ADVIA Centaur Cleaning Solution Concentrate
Version:	3.0

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Signature:

Mary Seeger
Sr. Director, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date
[YYYY-MM-DD]

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Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY, 10591, USA
Place of Manufacture:	Siemens Healthcare Diagnostics Manufacturing Ltd. Northern Road, Chilton Industrial Estate Sudbury, Suffolk, CO10 2XQ, UK and Fisher Diagnostics A division of Fisher Scientific Company, LLC A part of Thermo Fisher Scientific, Inc. 8365 Valley Pike Middletown, VA, 22645, USA
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Wash 1
Catalogue Number (REF):	01137199 (2 x 1.5 L) 03773025 (2 x 2.5 L)
Siemens Material Number (SMN):	10310032 (2 x 1.5 L) 10319550 (2 x 2.5 L)
Legacy Product Code:	112351 (2 x 1.5 L) N/A (2 x 2.5 L)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_ADVIA Centaur Wash 1
Version:	4.0

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EU Declaration of Conformity

Signature:

Matthew Gee
Sr. Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

2019-03-27

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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Place of Manufacture:	Siemens Healthcare Diagnostics Manufacturing Ltd. Northern Road, Chilton Industrial Estate Sudbury, Suffolk, CO10 2XQ, UK and Fisher Diagnostics A division of Fisher Scientific Company, LLC A part of Thermo Fisher Scientific, Inc. 8365 Valley Pike Middletown, VA, 22645, USA
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	ADVIA Centaur Acid/Base Reagents
Catalogue Number (REF):	03852677 (5000 tests) 00497043 (1000 tests)
Siemens Material Number (SMN):	10310026 (5000 tests) 10313526 (1000 tests)
Legacy Product Code:	112219 (5000 tests) N/A (1000 tests)
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_ADVIA Centaur Acid Base
Version:	4.0

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EU Declaration of Conformity

Signature:

Matthew Gee
Sr. Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

2019-03-27

Date
[YYYY-MM-DD]

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Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY, 10591, USA
Place of Manufacture:	<p>Carclo Technical Plastics Inc. 6009 Enterprise Drive Export, PA, 15632, USA</p> <p>or</p> <p>Carclo Technical Plastics Inc. 1141 West Grant Road Tucson, AZ, 85705, USA</p> <p>or</p> <p>Carclo Technical Plastics Ltd. 47 Wates Way Mitcham, Surrey, CR4 4HR, UK</p> <p>or</p> <p>CTP Taicang Co., Ltd 8 Xixin Road, Chengxiang Town Taicang, Jiangsu Province P.R. China 215411</p>
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	Cuvettes
Catalogue Number (REF):	10309546
Siemens Material Number (SMN):	10309546
Legacy Product Code:	078-K138-01 08044064
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_ADVIA Centaur Cuvettes
Version:	1.0

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Signature:

Matthew Gee
Sr. Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

2019-03-28

Date
[YYYY-MM-DD]

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EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	Sample Cups
Catalogue Number (REF):	10309545
Siemens Material Number (SMN):	10309545
Legacy Product Code:	078-K137-01 03832935
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_ADVIA Centaur Sample Cups
Version:	1.0

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Signature:

Matthew Gee
Sr. Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

2019-03-28

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EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	Disposable Sample Tips
Catalogue Number (REF):	10309547
Siemens Material Number (SMN):	10309547
Legacy Product Code:	078-K139-01 07413317
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_ADVIA Centaur Sample Tips
Version:	1.0

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Signature:

Matthew Gee
Sr. Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

2019-03-28

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