

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:

Seeger Mary

Digitally signed by Seeger Mary
DN: serialNumber=Z001YW2S, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.08.10 21:33:55 -04'00'

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

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

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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

Catalogue Number (REF): 07566733

Siemens Material Number (SMN): 10309508

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

Version: 4.0

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Signature:

Seeger Mary

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DN: serialNumber=Z001YW25, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.08.10 20:44:23 -04'00'

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

Date
[YYYY-MM-DD]

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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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Signature:

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givenName=Mary, sn=Seeger, o=Siemens,
cn=Seeger Mary
Date: 2019.08.10 20:39:23 -04'00'

Mary Seeger
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Tarrytown, NY, USA

Date
[YYYY-MM-DD]

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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 Ferritin

Catalogue Number (REF): 07875728 (1-pack)
00495776 (5-pack)

Siemens Material Number (SMN): 10309968 (1-pack)
10309969 (5-pack)

Legacy Product Code: 110745 (1-pack)
110746 (5-pack)

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ADVIA Centaur FER

Version: 2.0

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Signature:

Seeger Mary

Digitally signed by Seeger Mary
DN: serialNumber=Z001YW25, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.02.17 21:47:43 -05'00'

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

Date
[YYYY-MM-DD]

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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® BRAHMS Procalcitonin

Catalogue Number (REF): 11202697

Siemens Material Number (SMN): 11202697

Legacy Product Code: N/A

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: DoC_ADVIA Centaur BRAHMS Procalcitonin

Version: 2.0

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Signature:

Seeger Mary

Digitally signed by Seeger Mary
DN: serialNumber=Z001YW25, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.02.18 15:06:03 -05'00'

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

**Date
[YYYY-MM-DD]**

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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

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

Version: 4.0

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Signature:

Seeger Mary

Digitally signed by Seeger Mary
DN: serialNumber=Z001YW25, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.08.10 20:47:29 -04'00'

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

Date
[YYYY-MM-DD]

DECLARATION OF CONFORMITY

EU Declaration of Conformity



0197

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) Quality
Control

Catalogue Number (REF): 10376699

Siemens Material Number (SMN): 10376699

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 QC

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:

Robak Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF, givenName=Malgorzata,
sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.08.16 14:55:18 +01'00'

2019-08-16

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

**Date
[YYYY-MM-DD]**

ADVIA CENTAUR HBcT2 QC

SIEMENS

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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 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:

Seeger Mary

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DN: serialNumber=Z001YW25, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.08.10 20:42:34 -04'00'

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

Date
[YYYY-MM-DD]

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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 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

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Signature:

Seeger Mary

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DN: serialNumber=Z001YW2S, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.08.10 20:36:13 -04'00'

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

Date
[YYYY-MM-DD]

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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® BRAHMS Procalcitonin Quality Control Material

Catalogue Number (REF): 11202698

Siemens Material Number (SMN): 11202698

Legacy Product Code: N/A

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: DoC_ADVIA Centaur BRAHMS PCT QC

Version: 2.0

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Signature:

Seeger Mary

Digitally signed by Seeger Mary
DN: serialNumber=Z001YW25, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.02.18 15:09:27 -05'00'

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

Date
[YYYY-MM-DD]

REGISTRATION OF CONFORMITY

SIEMENS

EC Declaration of Conformity



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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 C

Catalogue Number (REF): 03439230 (2-pack)
06567787 (6-pack)

Siemens Material Number (SMN): 10311568 (2-pack)
10311575 (6-pack)

Legacy Product Code: 672172 (2-pack)
672182 (6-pack)

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ADVIA Centaur Cal C

Version: 2.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
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Signature: Seeger Mary Digitally signed by Seeger Mary
DN: serialNumber=Z001YW25, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.02.20 18:36:40 -05'00'

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

Date
[YYYY-MM-DD]

DECLARATION OF CONFORMITY

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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 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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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:

Seeger Mary

Digitally signed by Seeger Mary
DN: serialNumber=Z001YW25, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.02.17 00:45:03 -05'00'

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

Date
[YYYY-MM-DD]

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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:

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sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.02.17 00:45:03 -05'00'

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

Date
[YYYY-MM-DD]

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Document No. DoC_ADVIA Centaur APW1 Ver. 2.0

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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

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

Signature:

Seeger Mary

Digitally signed by Seeger Mary
DN: serialNumber=Z001YW25, givenName=Mary,
sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.02.20 01:03:43 -05'00'

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

Date
[YYYY-MM-DD]