SIEMENS

EU Declaration of Conformity

Digitally signed by Marinescu Traian alin
Date: 2022.03.10 08:52:27 EET
Reason: MoldSign Signature
Location: Moldova

CE 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 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]

SIEMENS

EU Declaration of Conformity

CE 0197

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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 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

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 20:44:23 -04'00'

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

Date
[YYYY-MM-DD]

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
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

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=Z001YW2S, givenName=Mary, sn=Seeger, o=Siemens, cn=Seeger Mary
Date: 2019.08.10 20:39:23 -04'00'

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

Date
[YYYY-MM-DD]

SIEMENS

EC 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
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

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: 2019.02.17 21:47:43 -05'00'

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

Date
[YYYY-MM-DD]

EU Declaration of Conformity

CE

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, 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® 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

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=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]

SIEMENS

EU Declaration of Conformity

CE 0197

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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 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

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 20:47:29 -04'00'

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

Date
[YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE
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]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE
0088

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 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

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 20:42:34 -04'00'

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

Date
[YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE
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 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.
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 20:36:13 -04'00'

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

Date
[YYYY-MM-DD]

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® 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

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=Z001YW2S, 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]

SIEMENS

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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 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=Z001YW2S, 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]

SIEMENS

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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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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

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=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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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

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=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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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

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=Z001YW2S, 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]

EC DECLARATION OF CONFORMITY