DECLARATION OF CONFORMITY

ATELLICA UAS 800 AND ATELLICA 1500 UAS

SIEMENS Healthineers

EU DECLARATION OF CONFORMITY

LEGAL MANUFACTURER	SIEMENS Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591 USA
PLACE OF MANUFACTURER	77 Elektronika Müszeripari Kft Fehérvári út 98 1116 Budapest HUNGARY
EU AUTHORIZED REPRESENTATIVE	SIEMENS Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin IRELAND
PRODUCT	**Atellica™ UAS 800 Analyzer and Atellica 1500 Automated Urinalysis System**
PRODUCT CATEGORY	See **TABLE I**
CLASSIFICATION	Self-Declaration
CONFORMITY ASSESSMENT ROUTE	Annex III Applied

STANDARDS APPLIED

ISO 13485:2016	MEDICAL DEVICES - Quality Management System Requirements - Requirements for Regulatory Purposes
EN ISO 14971:2019	MEDICAL DEVICES - Application of Risk Management to Medical Devices
EN ISO 18113-1:2011	In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labeling) PART 1: Terms, definitions, and general requirements
EN ISO 18113-3:2011	In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labeling) PART 3: In vitro diagnostic instruments for professional use
EN IEC 63000:2018	Technical Documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Digitally signed by Marinescu Traian alin
Date: 2023.05.19 11:34:23 EEST
Reason: MoldSign Signature
Location: Moldova

DECLARATION OF CONFORMITY

ATELLICA UAS 800 AND ATELLICA 1500 UAS

SIEMENS Healthineers

EU DECLARATION OF CONFORMITY

STANDARDS APPLIED (continued)

ISO 15223-1:2012	Symbols to be used with Medical Device Labels, Labeling and Information to be supplied – PART 1: General Requirements
ISO 15223-2:2010	Symbols to be used with Medical Device Labels, Labeling, and Information to be Supplied — PART 2: Symbol Development, Selection and Validation
IEC 62366:2008	Medical Devices – Application of Usability Engineering to Medical Devices
IEC 62304:2006	Medical Devices Software – Software Life-Cycle Processes
IEC / EN 61010-1:2010	Safety requirements for Electrical Equipment for measurement, control, and laboratory use – PART 1: General Requirements
IEC / EN 61010-2-101:2015	Safety requirements for Electrical Equipment for measurement, control, and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-020:2016	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-020: Particular requirements for laboratory centrifuges
IEC / EN 61010-2-081:2015	Safety requirements for Electrical Equipment for measurement, control, and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 980:2008	Symbols for use in the labelling of medical devices
EN 60825-1:2007	Safety of laser products – Part 1: Equipment classification and requirements
EN/IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General requirements
EN/IEC 61326-2-6:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

DECLARATION OF CONFORMITY

ATELLICA UAS 800 AND ATELLICA 1500 UAS

SIEMENS Healthineers

EU DECLARATION OF CONFORMITY

We herewith declare that the below-mentioned product(s) meet the provisions of the Council Directive 98/79/EC and elements specified in the RoHS Directive 2011/65/EU as amended by Amendment 2015/863/EU for *in vitro* diagnostic medical devices therefore have fulfilled all requirements for applying the CE mark to the *in vitro* Medical Device(s). The Manufacturer retains all supporting documentation.

ATTACHMENT I

ATELLICA UAS 800 ANALYZER		
SMN	**DESCRIPTION**	**CLASSIFICATION**
11065004	Atellica™ UAS 800 Analyzer	IVD – CE Mark / Analyzer

ATELLICA 1500AUTOMATED URINALYSIS SYSTEM		
SMN	**DESCRIPTION**	**CLASSIFICATION**
11065004	Atellica™ UAS 800 Analyzer	IVD – CE Mark / Analyzer

CONSUMABLES		
SMN	**DESCRIPTION**	**CLASSIFICATION**
11065553	Atellica™ UAS 800 Analyzer Cuvettes, (QTY 600)	IVD – CE Mark / Consumable

SOFTWARE UPGRADE KITS		
SMN	**DESCRIPTION**	**CLASSIFICATION**
10736617	Atellica™ UAS 800 V.4.0.100 Upgrade Kit	IVD – CE Mark / Software
10736529	Atellica™ UAS 800 V.4.0.120 Upgrade Kit	IVD – CE Mark / Software
10736542	Atellica™ UAS 800 V.4.0.200 Upgrade Kit	IVD – CE Mark / Software
11317715	Atellica™ UAS 800 V.4.0.220 Upgrade Kit	IVD – CE Mark / Software

END OF LIST

Siemens Healthcare Diagnostics, Inc.

Jun Yan

Electronically signed by Jun (EXT) Yan Reason: I am approving this document Date: Mar 18, 2022 13:06 EDT

Jun Yan
Regulatory Affairs Specialist

Mar 18, 2022

Date

Declaration of Conformity

CLINITEK ATLAS CONTROLS
(Negative and Positive Controls)
DMS 22-02-02 Rev 10.0

SIEMENS Healthineers

LEGAL MAUNFACTURER	Siemens Healthcare Diagnostics, Inc. 511 Benedict Avenue Tarreytown, NY 10591 USA
PLACE OF MANUFACTURE	Siemens Healthcare Diagnostics, Inc. 430 South Beiger Street Mishawaka, IN 46544 USA
EU AUTHORIZED REPRESENTATIVE	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
PRODUCT	CLINITEK ATLAS (Negative and Positive Control Strips)
PRODUCT LIST	See Attachment I
CLASSIFICATION	Self-Declaration
CONFORMITY ASSESSMENT ROUTE	Annex III Applied
DOC CONTROL NO.	DMS 22-02-02 Rev 10.0

STANDARDS APPLIED

ISO 13485:2016	Medical Devices – Quality Management System Requirements - Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN 13612:2002	Performance Evaluation of In Vito Diagnostic Medical Devices
EN 13640:2002	Stability Testing of In Vitro Diagnostic Medical Devices
EN 13641:2002	Eliminiation or Reduction of Risk of Infection Related to In Vitro Diagonostic Reagents
EN 980:2008	Grpahical Symbols to be used in the Labeling of Medical Devices.
ISO 15223-1:2012	Symbols to be Used with Medical Device Labels, Labeling, and Information to be supploies – **PART I**: General Requirements

Declaration of Conformity

CLINITEK ATLAS CONTROLS
(Negative and Positive Controls)
DMS 22-02-02 Rev 10.0

SIEMENS Healthineers

STANDARD APPLIED (*continued*)

ISO15223–2:2010	Symbols to be used with Medical Device labels, labeling, and information to be supplied - **PART 2:** Symbol development, selection and validation
EN ISO 17511:2003	In Vitro Diagnositc Medical Devices – Measurement of Quantities in Biological Samples – Metrological Traceability of Values Assigned to Claibrators and Control Materials
EN ISO 18113 - 1:2011	In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labeling) - **PART 1***: Terms, Definitions and General Requirements*
EN ISO 18113 - 2:2011	In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labeling) – **PART 2***: In vitro diagnostic reagents for professional use.*
EN ISO 18113 - 3:2011	In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labeling) – **PART 3***: In vitro diagnostic Instruments for professional use.*
IEC 61010-1:2001 (2nd Edition)	Safety requirements for electrical equipment for measurement, control, and laboratory use. **PART 1***: General Requirements.*
IEC 61010-2-081:2001 (1st Edition)	Safety requirements for electrical equipment for measurement, control, and laboratory use. **PART 2-081***: Particular requirements for Automatic and Semi-automatic Laboratory Equipment for Analysis and Other.*
IEC 61010-2-101:2001 (2nd Edition)	Safety requirements for electrical equipment for measurement, control, and laboratory use. **PART 2-101***: Particular requirements for In Vitro Diagnostic (IVD) Medical Equipment.*
IEC 60825-1:1993 (1st Edition)	With Amendment No. 1 (1997) and Amendment No. 1 (2001) – Safety of Laser Products **PART 1***: Equipment Classification, Requirements and User's Guide (depends on whether the laser or diode is Class 1 or higher)*
EN 61326-1:2006	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements Part 1: General Requirements – IEC 61326-1:2005; :1997

Declaration of Conformity

CLINITEK ATLAS CONTROLS
(Negative and Positive Controls)
DMS 22-02-02 Rev 10.0

SIEMENS Healthineers

STANDARD APPLIED (*continued*)

EN 61000-3-2:2006	Electromagnetic Compatibility (EMC) – Part 3-2: Limits - Limits for Harmonic Current Emissions (Equipment input greater than or equal to16A per phase) – IEC 61000-3-2:2005
EN 61000-3-3:1995	Electromagnetic Compatibility (EMC) – Part 3: Limits – Section 3 – Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems, for Equipment with rated Current Less than or equal to 16A per Phase and not subject to conditional connection.
EN IEC 62304:2006	Medical Device Software – Software Lifecycle Processes

Declaration of Conformity

CLINITEK ATLAS CONTROLS
(Negative and Positive Controls)
DMS 22-02-02 Rev 10.0

SIEMENS Healthineers

We herewith declare that the belw-mention product(s) meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices therefore has fulfilled all requirements for applying the CE mark to the Medical Devices(s). The Manufacturer retains all supporting documentation.

ATTACHMENT 1

SMN	REF/BAN	PRODUCT CODE	DESCRIPTION
10311135	03922594	5037	CLINITEK ATLAS Negative Control Strips
10311124	09204200	5019	CLINITEK ATLAS Positive Control Strips

END LIST

Novesteras Jim

Digitally signed by Novesteras Jim
DN: serialNumber=Z003W8MR, givenName=Jim, sn=Novesteras, o=Siemens, cn=Novesteras Jim
Date: 2019.03.04 18:47:53 -05'00'

Jim Novesteras
Regulatory Affairs Associate

DATE

DECLARATION OF CONFORMITY

LEGAL MANUFACTURER	Siemens Healthcare Diagnostics, Inc. 511 Benedict Avenue Tarrytown, NY 10591-5097 USA
PLACE OF MANUFACTUER	Siemens Healthcare Diagnostics, Inc. 430 Beiger Street Mishawaka, IN 46544 USA
EU AUTHORIZED REPRESENTATIVE	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
PRODUCT	CLINITEK Novus™ 10 Urinalysis Cassette CLINITEK Novus™ PRO 12 Urinalysis Cassette
DOCUMENT CONTROL NO.	DMS 22-02-02B Rev 6.0
PRODUCT CATEGORY	See Attachment 1
CLASSIFICATION	Self Declaration
COMFORMITY ASSESSMENT ROUTE	Annex III Applied

STANDARDS APPLIED

EN ISO 9001:2008	*Quality Management System Requirements*
EN ISO 13485:2012 / ISO 13485:2016	*Quality Management System for Medical Devices*
ISO 14971:2012	*Medical Devices- Application of Risk Management to Medical Device*
EN 375:2001	*Information supplied by the manufacturer with In Vitro Diagnostic Reagents for Professional Use*
EN 980:2008	*Symbols for Use in the Labeling of Medical Devices*
ISO 18113:2009	*In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labeling)* ***PART 1:*** *Terms, Definitions and General Requirements*

Declaration of Conformity

CLINITEK Novus 10 and CLINITEK PRO 12
Urinalysis Cassettes

SIEMENS Healthineers

DMS 22-02-02B **Rev 6.0**

STANDARDS APPLIED
(continued)

EN 13612:2002	*Performance Evaluation of In Vitro Diagnostic Medical Devices*
IEC 61010-1:2001	*Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use* ***PART 1:*** *General Requirements*
IEC 61010-2-081:2001 (1st Edition) Amended 1-2003	*Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use*
IEC 61010-2-101:2002	*Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use*
UL 61010-1:2001	*Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use*
EN 61010-2-081:2003	*Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use*
EN 61010-2-101:2002	*Safety Requirements for Electrical Equipment for Measurement Control and Laboratory Use*
UL 61010-1:2008	*Electrical Equipment for Measurement, Control, and Laboratory Use;* ***PART 1:*** *General Requirements*
EN 60825-1:2007	*Safety of Laser Products Equipment Classification and Requirements*
IEC/EN 61326-1:2008 *(2nd Edition)*	*Electrical Equipment for Measurement, Control, and Laboratory Use*
IEC/EN 61326-1:2012 *(1st Edition)*	*Electrical Equipment for Measurement, Control, and Laboratory Use*
EN 62366:2008	*Medical Device Application of Usability Engineering to Medical Devices*

Declaration of Conformity

CLINITEK Novus 10 and CLINITEK PRO 12
Urinalysis Cassettes

SIEMENS Healthineers

DMS 22-02-02B **Rev 6.0**

We herewith declare that the product(s) listed below meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and therefore has fulfilled all requirements for applying for the CE mark to the Medical Device(s). The Manufacturer retains all supporting documentation.

ATTACHMENT 1

SMN	Product Code	Description
10634643	10634643	CLINITEK™ Novus 10 Urinalysis Cassette
10634644	10634644	CLINITEK Novus PRO 12 Urinalysis Cassette

End List

Novesteras Jim

Digitally signed by Novesteras Jim
DN: serialNumber=Z003W8MR, givenName=Jim, sn=Novesteras, o=Siemens, cn=Novesteras Jim
Date: 2019.03.05 17:14:23 -05'00'

Jim Novesteras
Regulatory Affairs Associate

Date

EU DECLARATION OF CONFORMITY

Manufacturer	
Name:	*Siemens Healthcare Diagnostics Inc.*
Address:	*511 Benedict Avenue,* *Tarrytown, NY 10591 USA*
Single Registration Number (SRN):	*US-MF-000016560*
Authorized Representative	
Name:	*Siemens Healthcare Diagnostics Manufacturing Ltd.*
Address:	*Chapel Lane,* *Swords, Co. Dublin, Ireland*
SRN Authorized Representative:	*IE-AR-000006763*
Manufacturing Facility	
Name:	*Fisher Diagnostics Inc. (a division of Fisher Scientific Company LLC)*
Address:	*8365 Valley Pike,* *Middletown, VA 22645 USA*
Product Identification	See Product Identification table

We declare that the in vitro diagnostic medical device(s) listed in the Product Identification table is/are in conformity with the following legislation(s):

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

The conformity of the quality management system is declared according to Article 48.

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 products.

On Behalf of Siemens Healthcare Diagnostics Inc.:

Place and date *Norwood, 12 May 2022*

Signature:

Electronically signed by:
Darius Daruwala
Reason: I am approving this document
Date: May 12, 2022 14:08 EDT

Email: darius.daruwala@siemens-healthineers.com

Darius Daruwala
Manager, Regulatory Affairs

Product Identification Table

Product/ Trade Name	Model	Basic UDI-DI	Risk Class	Intended Purpose
CLINITEK Novus Rinse Additive	10697754	0405686901928WD	**Class A** (According to rule 5 Annex VIII In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746)	The CLINITEK Novus® Rinse Additive is diluted for use as the rinse solution in the CLINITEK Novus Automated Urine Chemistry System. This product is for professional, in vitro diagnostic use for clinical laboratory use.
CLINITEK Novus Rinse Additive	11561556			