

Declaration of Conformity

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

PLACE OF MANUFACTURE: Kimball Electronics Poland Sp z o.o.
ul. Poznanska 1/C
Tarnowo Podgorne Poland 62080

PRODUCT: Urinalysis Visual & Instrument Test Strips

PRODUCT CATEGORY: See Attachment 1

CLASSIFICATION: Self Declaration

CONFORMITY ASSESSMENT ROUTE: Annex III Applied

STANDARDS APPLIED: ISO 13485:2003 – Medical Devices - Quality Management Systems for Medical Devices
EN 13612:2002 – Performance Evaluation of In Vitro Diagnostic Medical Devices
EN 13640:2002 – Stability Testing of In Vitro Diagnostic Reagents
EN ISO 14971:2009 – Medical Devices- Application of Risk Management to Medical Devices
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
EN ISO 17511:2003 – In Vitro Diagnostic Medical Devices – Measurement of Quantities in Biological Samples – Metrological Traceability of Values Assigned to Calibrators and Control Materials
EN ISO 18113-1:2011 – In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 1: Terms, Definitions and General Requirements
EN ISO 18113-2:2011 - In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 2: In Vitro Diagnostics Reagents for Professional Use

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA


Susan Tibedo


Date

Sr. Manager – Regulatory - POC

Declaration of Conformity

We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

Attachment 1		
REF (BAN) /SMN	Product Code	Description
03783489 / 10319565	A2292C52	Multistix 10 SG Latin (25)
05328339 / 10322360	A2300A29	Multistix 10 SG Nordic
03536597 / 10319133	A2300C51	Multistix 10 SG Europe
00718686 / 10313959	A2300C52	Multistix 10 SG Latin (100)
04200746 / 10320335	A2304C51	Multistix 8 SG Europe (50)
05258055 / 10322217	A2304D29	Multistix 8 SG Nordic (100)
08646323 / 10328579	A2087A52	Microalbustix
09159477 / 10328660	A2289A52	Multistix 8 SG Latin
01211267 / 10314818	A2305D29	Multistix 7 Nordic
07900226 / 10327186	A2740C51	N-Multistix SG Europe
07771019 / 10326937	A2740C52	N-Multistix SG Latin
08259974 / 10327901	A2810C51	Labstix Europe
02827164 / 10317784	A2810C52	Labstix Latin
04581138 / 10320975	A2810F29	Labstix Nordic
05205326 / 10322126	A2857C51	Uristix Europe
01037046 / 10314513	A2857C52	Uristix Latin
04010718 / 10300006	A2857E29	Uristix Nordic
06562467 / 10324743	A2877C51	Hema-Combistix Europe

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 11 Jun 2014
Susan Tibedo Date
Sr. Manager – Regulatory - POC



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REF (BAN) /SMN	Product Code	Description
05798300 / 10323220	A2330B50	Multistix 10 Visual
04960872 / 10321658	A2087B51	Microalbustix
04624902 / 10321054	A2283J01	Multistix GP UK/Spain
03570159 / 10319183	A2291C18	Multistix 10 SG Germany
02156642 / 10316556	A2300B21	Multistix 10 SG
03390851 / 10318865	A2300C40	Multistix 10 SG
06565954 / 10324751	A2308A52	Multistix 5
07500392 / 10326466	A2308C29	Multistix 5
03242542 / 10318564	A2308C51	Multistix 5
08955414 / 10329106	A2741B51	Multistix SG
04240977 / 10320395	A2743J01	Labstix SG
07571427 / 10326594	A2815C51	N-Labstix
00828708 / 10314160	A2820C51	Multistix
05441720 / 10322559	A2825C18	N-Neostix
01526748 / 10315394	A2300D18	Multistix 10 SG
		End of List

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Susan Tibedo
Sr. Manager – Regulatory - POC

11 Jun 2014
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LEGAL MANUFACTURER: Siemens Healthcare Diagnostics Inc.
Tarrytown, New York 10591-5097
USA

PLACE OF MANUFACTURE: Siemens Healthcare Diagnostics Manufacturing
Ltd.
Northern Road, Chilton Industrial Estate
Sudbury, Suffolk CO10 2XQ
U.K

PRODUCT: Clinitek Status+ Analyzer

PRODUCT CATEGORY: See attachment 1

CLASSIFICATION: Self Declaration

CONFORMITY ASSESSMENT ROUTE: ANNEX III Applied

STANDARDS APPLIED: ENISO14971:2007 - Application of risk management
to Medical Devices

EN980:2008 - Graphical symbols for use in the
labeling of Medical Devices.

EN13612:2002 - Performance Evaluation of In Vitro
Diagnostic Medical Devices

ENISO13485:2003 – Quality System for Medical
Devices

ISO 15223– 1: 2007: 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

EN 62366:2008 – Medical devices – Application of
usability engineering to medical devices.

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Susan Tibedo
Senior Manager, Regulatory Affairs - POC

21 Apr 2014
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Declaration of Conformity

STANDARDS APPLIED:

EN60601-1-2:2007 - Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class A for non-life supporting equipment

EN60601-1-2:Ed.2.1 Electromagnetic emissions and immunity requirements for medical electrical equipment –group 1 equipment, class A for non-life supporting equipment

EMC Emission and Immunity


UI 61010a-1 (2002) Safety requirements for electrical equipment for laboratory use Part 1: General requirements

IEC 61010-1(1990) +A1(1991)+ A2(1995) Safety requirements for electrical equipment for

measurement, control and laboratory use Part 1

CAN/CSAC22.2 No. 1010.1-92 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements

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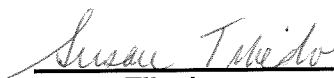
 21 Apr 2014
Susan Tibedo Date
Senior Manager, Regulatory Affairs - POC

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		Attachment 1
REF (BAN) /SMN	Product Code	Description
10376322	10337622	Clinitek Status Connector WW
10379676	10379676	Clinitek Status + UK
10379676	10379677	Clinitek Status+ European
10379677	10379678	Clinitek Status+ French
10379678	10379679	Clinitek Status+ German
10379679	10379680	Clinitek Status+ Japanese
10379680	10379681	Clinitek Status+Chinese
10844416	10844416	Clinitek Status+2.5/2.3 SW Upgrade Kit
		End of List

Siemens Healthcare Diagnostics Inc.
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 21 Apr 2014
Susan Tibedo Date
Senior Manager, Regulatory Affairs - POC