SIEMENS

Declaration of Conformity

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.**

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

Susan Tibedo 21 Apr 2014

Susan Tibedo **Date**
Senior Manager, Regulatory Affairs - POC

SIEMENS

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

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

Susan Tibedo 21 Apr 2014

Susan Tibedo **Date**
Senior Manager, Regulatory Affairs - POC

SIEMENS

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**
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.
Norwood, Massachusetts, USA

Susan Tibedo 21 Apr 2014

Susan Tibedo **Date**
Senior Manager, Regulatory Affairs - POC