

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
Senior Manager, Regulatory Affairs - POC

21 Apr 2014
Date

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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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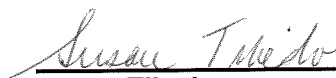
 21 Apr 2014
Susan Tibedo Date
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We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

		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

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 21 Apr 2014
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