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**
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.**

Digitally signed by Marinescu Traian alin
Date: 2025.02.18 12:21:11 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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
IVDD 98/79/EC
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)	**Product Code**	**Description**
04635602	201	Clinitek Status German
04636536	202	Clinitek Status Italian
04638598	203	Clinitek Status Spanish
04638997	204	Clinitek Status Swedish
04640401	205	Clinitek Status Generic
05032537	206	Clinitek Status French
05033460	207	Clinitek Status UK
05964812	208	Clinitek Status Norwegian
05966912	209	Clinitek Status Dutch
05967714	210	Clinitek Status Finnish
05968591	211	Clinitek Status Danish
05969032	212	Clinitek Status Polish
05969342	213	Clinitek Status Portuguese
06758574	214	Clinitek Status - Mera
06255246	215	Clinitek Status PSU UK
06256331	216	Clinitek Status PSU EU
06256684	217	Clinitek Status PSU Universal
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