SIEMENS

# Declaration of Conformity

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|---|---|
| **LEGAL MANUFACTURER:** | **Siemens Healthcare Diagnostics Inc.<br>511 Benedict Road<br>Tarrytown, New York 10591-5097<br>USA** |
| **PLACE OF MANUFACTURE:** | **Siemens Healthcare Diagnostics Manufacturing Ltd.<br>Northern Road, Chilton Industrial Estate<br>Sudbury, Suffolk CO10 2XQ<br>U.K** |
| **PRODUCT:** | **CLINITEK Status+ Analyzer** |
| **PRODUCT CATEGORY:** | **See attachment 1** |
| **CLASSIFICATION:** | **Self Declaration** |
| **CONFORMITY ASSESSMENT ROUTE:** | **ANNEX III Applied** |
| **STANDARDS APPLIED:** | **EN ISO 14971:2009 - Medical devices - Application of risk management to medical devices<br>ISO 13485:2003 – Medical devices -- Quality Management Systems -- Requirements for Regulatory Purposes<br>EN ISO 18113-1:2011 - In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements<br>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<br>EN 13612:2002 - Performance Evaluation of In Vitro Diagnostic Medical Devices<br>ISO 15223– 1: 2012: Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements<br>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<br>EN 62366:2008 – Medical devices – Application of usability engineering to medical devices.<br>EN 62304:2006 - Medical device software - Software life-cycle processes** |

**Siemens Healthcare Diagnostics Inc.**
**Norwood, Massachusetts, USA**

Susan Tibedo 11 Feb 2015

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

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**STANDARDS APPLIED:**

**IEC/EN 61010-1:2001 (2nd Edition) - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements**

**IEC/EN 61010-2-081:2002 (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 purposes**

**IEC/EN 61010-2-101:2002 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment**

**CAN/CSA C22.2 No. 61010-1:2004 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements. Certification Body must be accredited by the Standards Council of Canada.**

**CAN/CSA C22.2 No. 61010-2-081:2004 - 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 purposes**

**CAN/CSA C22.2 No. 61010-2-101:2004 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment**

**UL 61010-1-2008 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements. Certification Body must be a Nationally Recognized Testing Laboratory authorized by the Occupational Safety & Health Administration.**

**EN 60601-1-2:2007 - Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment**

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**IEC 60601-1-2 Ed. 2.1 - Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment**
**2002/96/EC - Council Directive 2002/96/EC relating to the waste of electrical and electronic equipment (WEEE)**

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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 | 10376322 | Clinitek Status Connector WW |
| 10376323 | 10376323 | CLINITEK Status Connector USA |
| 10379676 | 10379676 | Clinitek Status + UK |
| 10379677 | 10379677 | Clinitek Status+ European |
| 10379678 | 10379678 | Clinitek Status+ French |
| 10379679 | 10379679 | Clinitek Status+ German |
| 10379680 | 10379680 | Clinitek Status+ Japanese |
| 10379681 | 10379681 | Clinitek Status+Chinese |
| 10379675 | 10379675 | CLINITEK Status+ USA |
| 10844416 | 10844416 | Clinitek Status+2.5/2.3 SW Upgrade Kit |
| 10844875 | 10844875 | CLINITEK Status+ 2.6 SW Upgrade Kit MMC (OUS) |
| 10845305 | 10845305 | CLINITEK Status+ 2.6 SW Upgrade Kit MMC (US) |
| 10844420 | 10844420 | CLINITEK Status+ / Connector 2.6/2.4.0.0 SW Upgrade Kit (OUS) |
| 10719594 | 10719594 | CLINITEK Status+ / Connector 2.6/2.4.0.0 SW Upgrade Kit (US) |
| | | End of List |

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