SIEMENS

Declaration of Conformity

LEGAL MANUFACTURER:	**Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591-5097 USA**
PLACE OF MANUFACTURE:	**Siemens Healthcare Diagnostics Manufacturing Ltd. Northern Road, Chilton Industrial Estate Sudbury, Suffolk, UK CO10 2XQ**
EU AUTHORIZED REPRESENTATIVE	**Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland**
NOTIFIED BODY	**TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197**
PRODUCT:	**DCA Vantage® Analyzer (Self-Test) Please see Table 1 for the complete list of products**
CLASSIFICATION:	**In Vitro Diagnostic Medical Device for Self-Testing (non-Annex II List A or List B)**
CONFORMITY ASSESSMENT ROUTE:	**Annex III.6 OF Directive 98/79/EC**

STANDARDS APPLIED:

- **Directive 98/79/EC – In Vitro Diagnostic Medical Devices (IVD Directive)**
- **ISO 13485:2016 – Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes**
- **EN ISO14971:2012 - Medical Devices-Application of Risk Management to Medical Devices**
- **EN ISO 18113-1:2011 – In vitro diagnostic medical devices - Information Supplied by the Manufacturer (Labeling) Part 1: Terms, definitions and general requirements**
- **EN ISO 18113-5: 2011 *In vitro* diagnostic medical devices-Information supplied by the manufacturer (Labelling) Part 5: In vitro diagnostic instruments for self-testing**
- **ISO 15223-1:2012: Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements**
- **ISO 15223–2:2010: Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied—Part 2: Symbol development, selection and validation**
- **EN13612:2002 - Performance evaluation of in vitro diagnostics medical devices**
- **IEC 61326-1:2005 Edition1.0– Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General requirements**
- **IEC 61326-2-6:2005 Edition 1.0 - Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment**

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- **FCC 47CFR Part 15:2012 Subpart B Class B**
- **IEC/EN 61010-1:2010 (Third Edition) - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements**
- **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**
- **IEC 61010-2-081:2001+A1:2003 - 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**
- **EN 61010-2-081:2002 - 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**
- **UL 61010-1:2008 - Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory use**
- **CAN/CSA C22.2 No. 61010-1-09 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements**
- **CAN/CSA C22.2 No. 61010-2-081:2009 - 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. 61010-2-101:2009 - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment**
- **ISTA 1a - Non-Simulation Integrity Performance Tests: Packaged-Products weighing 150 lb (68 kg) or Less**
- **EN 62366:2008 – Medical devices – Application of usability engineering to medical devices.**
- **EN IEC 62304: 2006 - Medical device software - Software life-cycle processes**
- **EN 50581:2012 – Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.**

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We herewith declare that the below-mentioned product(s) meet the provisions of the Council Directive 98/79/EC and elements specified in Annex VI of RoHS Directive 2011/65/EU for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

Table 1

SMN	REF (BAN)	Product Code	Description
10845062	10845062	10845062	DCA Vantage® Analyzer (Self-Test)

Novesteras Jim

Digitally signed by Novesteras Jim
DN: serialNumber=Z003W8MR, givenName=Jim, sn=Novesteras, o=Siemens, cn=Novesteras Jim
Date: 2019.07.30 14:28:40 -04'00'

Jim Novesteras
Regulatory Affairs Associate

Date

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA