DCA Vantage® Analyzer



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PRODUCT DCA Vantage® Analyzer

PRODUCT CATEGORY See **TABLE I**

CLASSIFICATION Self-Declaration

CONFORMITY ASSESSMENT ROUTE Annex III Applied

STANDARDS APPLIED

ISO 13485:2016 MEDICAL DEVICES - Quality Management System

Requirements - Requirements for Regulatory Purposes

EN ISO 14971:2019 MEDICAL DEVICES - Application of Risk Management to

Medical Devices

ISO 13612:2002 Performance Evaluation of In Vitro Diagnostic 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 18113-2:2011 IN VITRO DIAGNOSTIC MEDICAL DEVICES – Information

Supplied by the Manufacturer (Labeling) PART 2: In vitro

diagnostic reagents for professional use

EN ISO 18113-3:2011 IN VITRO DIAGNOSTIC MEDICAL DEVICES – Information

Supplied by the Manufacturer (Labeling) PART 3: In vitro

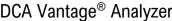
diagnostic instruments for professional use

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	STANDARDS APPLIED (continued)	
CONFORMITY	EN IEC 63000:2018	TECHNICAL DOCUMENTATION for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
RN	ISO 15223-1:2012	SYMBOLS to be used with Medical Device Labels, Labeling and Information to be supplied – PART 1: General Requirements
NFC	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
O	IEC 62366:2008	MEDICAL DEVICES – Application of Usability Engineering to Medical Devices
0	IEC 62304:2006	MEDICAL DEVICES SOFTWARE – Software Life-Cycle Processes
0	IEC 61326-1:2005	EDITION 2.0 ELECTRICAL EQUIPMENT for measurement control and laboratory use – EMC Requirements
N	EN 61326-2-6:2006	ELECTRICAL EQUIPMENT for measurement, control, and laboratory use - EMC requirements - PART 2 - 6: Particular requirements - In vitro diagnostic (IVD) medical equipment
√TI(IEC / EN 61010-1:2001	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT for measurement, control, and laboratory use – PART 1: General Requirements
-AR/	IEC / EN 61010-2-101:2002	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT for measurement, control, and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment
DECLARATION OF	IEC / EN 61010-2-081:2002	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT for measurement, control, and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EU	UL 61010-1:2008	ELECTRICAL EQUIPMENT for measurement, control, and laboratory use; PART 1: General Requirement





SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT for Measurement, Control, and Laboratory Use - PART 1: General requirements
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
SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT for Measurement, Control and Laboratory Use - PART 2 - 101: Particular requirements for In Vitro Diagnostic (IVD) Medical Equipment
SAFETY OF LASER PRODUCTS – PART 1: Equipment classification and requirements

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DECLARATION OF CONFORMITY

We herewith declare that the below-mentioned product(s) meet the provisions of the Council Directive 98/79/EC and elements specified in the RoHS Directive 2011/65/EU as amended by Amendment 2015/863/EU for *in vitro* diagnostic medical devices therefore have fulfilled all requirements for applying the CE mark to the *in vitro* Medical Devices(s).

The Manufacturer retains all supporting documentation.

TABLE I

SMN	REF (BAN)	PRODUCT CODE	DESCRIPTION
10282970	06651932	5075WW	DCA Vantage® Analyzer
10282969	10282969	5075US	DCA Vantage [®] Analyzer
10631257	10631257	10631257	DCA V3.0 UPGRADE SOFTWARE KIT
10844657	10844657	10844657	DCA V4.0 UPGRADE SOFTWARE KIT

END OF LIST

Siemens Healthcare Diagnostics, Inc.

Suzane Orehan
Ressor: la major
this document
Date Mar 27 20 1

Suzanne Crehan Date

Regulatory Technical Professional

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