DECLARATION OF CONFORMITY

DCA Vantage® Analyzer

SIEMENS Healthineers

EU DECLARATION OF CONFORMITY

LEGAL MANUFACTURER	**SIEMENS Healthcare Diagnostics Inc.** 511 Benedict Avenue Tarrytown, New York 10591 USA
PLACE OF MANUFACTURER	**SIEMENS Healthcare Diagnostics, Manufacturing Ltd.** Northern Road, Chilton Industrial Estate Sudbury, Suffolk CO10 2XQ U.K.
EU AUTHORIZED REPRESENTATIVE	**SIEMENS Healthcare Diagnostics Manufacturing Ltd.** Chapel Lane Swords, Co. Dublin IRELAND
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

STANDARDS APPLIED (continued)

EN IEC 63000:2018	TECHNICAL DOCUMENTATION for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
ISO 15223-1:2012	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
IEC 62366:2008	MEDICAL DEVICES – Application of Usability Engineering to Medical Devices
IEC 62304:2006	MEDICAL DEVICES SOFTWARE – Software Life-Cycle Processes
IEC 61326-1:2005	EDITION 2.0 ELECTRICAL EQUIPMENT for measurement control and laboratory use – EMC Requirements
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
IEC / EN 61010-1:2001	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. Particular requirements for in vitro diagnostic (IVD) medical equipment
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
UL 61010-1:2008	ELECTRICAL EQUIPMENT for measurement, control, and laboratory use; PART 1: General Requirement

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STANDARDS APPLIED (continued)

CAN/CSA C22.2 No. 61010-1-2004	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT for Measurement, Control, and Laboratory Use - PART 1: General requirements
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
EN 60825-1:2007	SAFETY OF LASER PRODUCTS – PART 1: Equipment classification and requirements

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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 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.

Suzanne Crehan

Electronically signed by:
Suzanne Crehan
Reason: I am approving this document
Date: Mar 22, 2022 11:21 EDT

Suzanne Crehan Date
Regulatory Technical Professional