

<b>LEGAL MANUFACTURER:</b>	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591-5097 USA
<b>PLACE OF MANUFACTURE:</b>	Siemens Healthcare Diagnostics, Inc. 430 S. Beiger Street Mishawaka, Indiana 46544 USA
<b>EU AUTHORIZED REPRESENTATIVE</b>	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin IRELAND
<b>PRODUCT</b>	DCA Systems Reagents
<b>PRODUCT CATEGORY</b>	See attachment 1
<b>CLASSIFICATION</b>	Self Declaration
<b>CONFORMITY ASSESSMENT ROUTE</b>	ANNEX III Applied
<b>STANDARDS APPLIED</b>	
EN ISO 13485:2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN 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

**EU DECLARATION OF CONFORMITY**

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- 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

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**

SMN	REF (BAN)	Product Code	Description
10311134	06162000	C5035	DCA Systems Hemoglobin A1c Reagent Kit
10698915	10698915	10698915	DCA Systems HbA1c Reagent Kit
10311480	01443699	6011A	Microalbumin/Creatinine Reagent Kit
10888739	10888739	10888739	DCA Systems Microalbumin/Creatinine Capillary holders and plungers
10888741	10888741	10888741	DCA Systems Hemoglobin A1c Capillary holders

**End of List**

*Suzanne Crehan*

Electronically signed by: Suzanne Crehan  
Reason: I am the author of this document  
Date: May 3, 2021 18:19 EDT

Suzanne Crehan  
Regulatory Technical Professional

Date