DECLARATION OF CONFORMITY

Hemoglobin A1c Normal / Abnormal Control

EU DECLARATION OF CONFORMITY

LEGAL MANUFACTURER	SIEMENS Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591 USA
PLACE OF MANUFACTURER	Canterbury Scientific Ltd. 71 Whiteleigh Avenue, Addington Christchurch 8011 NEW ZEALAND
EU AUTHORIZED REPRESENTATIVE	SIEMENS Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin IRELAND
PRODUCT	**Hemoglobin A1c Normal / Abnormal**
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
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)

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,

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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* Diagnostic Medical Devices(s).
The Manufacturer retains all supporting documentation.

ATTACHMENT I

SMN	REF (BAN)	PRODUCT CODE	DESCRIPTION
10311161	03714363	5068A	DCA Systems Hemoglobin A1c Normal & Abnormal Control Kit

END OF LIST

Siemens Healthcare Diagnostics, Inc.

Signature: Amy Goldberg

Electronically signed by: Amy Goldberg
Reason: I am approving this document
Date: Jul 19, 2021 17:48 EDT

Email: AMY.GOLDBERG@SIEMENS-HEALTHINEERS.COM

July 19, 2021
Date

Amy Goldberg
Director, Regulatory Affairs

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