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, Inc. 430 S. Beiger Street Mishawaka, Indiana 46546 U.S.A.**
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 Systems Hemoglobin A1c Reagent Kit (Self-Test)**
PRODUCT LIST:	**See attachment 1**
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 ISO 14971:2012 - 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 18113-4:2011 – In vitro diagnostic medical devices - Information supplied by the Manufacturer (labeling) (Part 4): In vitro diagnostic reagents for self-testing.**

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

SIEMENS

Declaration of Conformity

STANDARDS APPLIED:

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.

EN13612:2002 - Performance evaluation of in vitro diagnostics medical devices.

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.

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

SIEMENS

Declaration of Conformity

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
10888639	10888639	10888639	DCA Systems HbA1C Reagent Kit

End of list

Novesteras Jim

Digitally signed by Novesteras Jim
DN: serialNumber=Z003W8MR, givenName=Jim, sn=Novesteras, o=Siemens, cn=Novesteras Jim
Date: 2019.07.22 09:48:43 -04'00'

Jim Novesteras
Regulatory Affairs Associate

Date

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA