DECLARATION OF CONFORMITY

URINE STRIPS – PROFESSIONAL USE / INSTRUMENT READ

SIEMENS Healthineers

EU DECLARATION OF CONFORMITY

LEGAL MANUFACTURER	SIEMENS Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591 USA
PLACE OF MANUFACTURER	Kimball Electronics Poland Sp z 0.0 ul. Poznanska 1/C Tarnowo Podgorne Poland 62080
EU AUTHORIZED REPRESENTATIVE	SIEMENS Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin IRELAND
PRODUCT	Urinalysis Strips Instrumentally Read Only & Urinalysis Strips Instrumentally Read with Visual Read
PRODUCT CATEGORY	See **TABLE I**
CLASSIFICATION	Self-Declaration
CONFORMITY ASSESSMENT ROUTE	Annex III Applied

STANDARDS APPLIED

EN ISO 13485:2016	Quality System for Medical Devices
EN 13612:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
EN 13641:2002	Elimination or Reduction of Risk of Infection Related to IVD Reagents
EN ISO 14971:2019	Medical Devices- Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Symbols to be Used with Medical Device Labels, Labeling, and Information to be Supplied- Part 1: General Requirements
EN ISO 18113-1:2011	In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 1: Terms, Definitions and General Requirements
EN ISO 18113-2:2011	In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 2: In Vitro Diagnostics Reagents for Professional Use
EN ISO 23640:2015	In Vitro Diagnostic Medical Devices – Evaluation of stability of In Vitro Diagnostic Reagents

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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 Device(s). The Manufacturer retains all supporting documentation.

This Declaration of Conformity (DoC) is updated pursuant to article 110.3 in conjunction with article 112 second paragraph of the Regulation (EU) 2017/746 (IVDR) and changes have been evaluated according to MDCG 2022-6 Guidance on significant changes regarding the transitional provisions under article 110.3 IVDR. The updates made to this DoC has been deemed non-significant.

TABLE I

SMN	REF (BAN)	PRODUCT CODE	DESCRIPTION
10285741	06916863	2093	CLINITEK Microalbumin 9
10285742	06916871	2093	CLINITEK Microalbumin 9
10318739	03330964	2083	CLINITEK Microalbumin 2
10317957	02924704	2083	CLINITEK Microalbumin 2
10318844	03378738	2083	CLINITEK Microalbumin 2
11306461	11306461	N/A	CLINITEK Microalbumin 2+

END OF LIST

Siemens Healthcare Diagnostics, Inc.

Ashli Austin

Electronically signed by: Ashli Austin
Reason: I am the author of this document
Date: May 5, 2023 10:56 EDT

Ashli Austin
Regulatory Affairs Specialist

Date