DECLARATION OF CONFORMITY

URINALYSIS VISUAL & INSTRUMENT TEST STRIPS

SIEMENS Healthineers

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 Visual & Instrument Test Strips
PRODUCT CATEGORY	See **TABLE I**
CLASSIFICATION	Self-Declaration
CONFORMITY ASSESSMENT ROUTE	Annex III Applied

STANDARDS APPLIED

ISO 13485:2016	Quality System for Medical Devices
ISO 13485:2016	Medical Devices – Quality Management Systems for Medical Devices
EN 13612:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
EN 13640:2002	Stability Testing of In Vitro Diagnostic Reagents
EN ISO 14971:2012	Medical Devices- Application of Risk Management to Medical Devices
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
EN ISO 17511:2003	In Vitro Diagnostic Medical Devices – Measurement of Quantities in Biological Samples – Metrological Traceability of Values Assigned to Calibrators and Control Materials

EU DECLARATION OF CONFORMITY

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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

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
10313959	00718686	A2300C52	Multistix 10 SG Latin (100)
10314160	00828708	A2820C51	Multistix
10314818	01211267	A2305D29	Multistix 7 Nordic
10315394	01526748	A2300D18	Multistix 10 SG
10316556	02156642	A2300B21	Multistix 10 SG
10318564	03242542	A2308C51	Multistix 5
10318865	03390851	A2300C40	Multistix 10 SG
10319133	03536597	A2300C51	Multistix 10 SG Europe
10319565	03783489	A2292C52	Multistix 10 SG Latin (25)
10320006	04010718	A2857E29	Uristix Nordic
10320335	04200746	A2304C51	Multistix 8 SG Europe (100)
10320395	04240977	A2743J01	Labstix SG
10321054	04624902	A2283J01	Multistix GP UK/Spain
10321658	04960872	A2087B51	Microalbustix
10322126	05205326	A2857C51	Uristix Europe
10322217	05258055	A2304D29	Multistix 8 SG Nordic (100)
10322360	05328339	A2300A29	Multistix 10 SG Nordic
10323220	05798300	A2330B50	Multistix 10 Visual
10324743	06562467	A2877C51	Hema-Combistix Europe
10324751	06565954	A2308A52	Multistix 5
10326466	07500392	A2308C29	Multistix 5
10326594	07571427	A2815C51	N-Labstix
10326937	07771019	A2740C52	N-Multistix SG Latin
10327901	08259974	A2810C51	Labstix Europe
10328579	08646323	A2087A52	Microalbustix

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SMN	REF (BAN)	PRODUCT CODE	DESCRIPTION
10329106	08955414	A2741B51	Multistix SG
10329509	09159477	A2289A52	Multistix 8 SG Europe (50)
11556050	11556050	A2331A60	Q-ity UA 10 Visual Strip

END OF LIST

Siemens Healthcare Diagnostics, Inc.

Ashli Austin

Electronically signed by: Ashli Austin
Reason: I am the author of this document
Date: Jan 23, 2023 15:38 EST

Ashli Austin
Regulatory Affairs Specialist

Date

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