SIEMENS

Declaration of Conformity

LEGAL MANUFACTURER:	**Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591-5097 USA**
PLACE OF MANUFACTURE:	**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 Attachment 1**
CLASSIFICATION:	**Self Declaration**
CONFORMITY ASSESSMENT ROUTE:	**Annex III Applied**
STANDARDS APPLIED:	**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 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**

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

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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) /SMN	Product Code	Description
10320006	04010718	A2857E29	Uristix Nordic
10313959	00718686	A2300C52	Multistix 10 SG Latin (100)
10314160	00828708	A2820C51	Multistix
10314513	01037046	A2857C52	Uristix Latin
10314818	01211267	A2305D29	Multistix 7 Nordic
10315394	01526748	A2300D18	Multistix 10 SG
10316556	02156642	A2300B21	Multistix 10 SG
10317784	02827164	A2810C52	Labstix Latin
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)
10320335	04200746	A2304C51	Multistix 8 SG Europe (100)
10320395	04240977	A2743J01	Labstix SG
10320975	04581138	A2810F29	Labstix Nordic
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
10322559	05441720	A2825C18	N-Neostix
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
10327186	07900226	A2740C51	N-Multistix SG Europe
10327901	08259974	A2810C51	Labstix Europe
10328579	08646323	A2087A52	Microalbustix
10329106	08955414	A2741B51	Multistix SG
10329509	09159477	A2289A52	Multistix 8 SG Europe (50)

Novesteras Jim

Digitally signed by Novesteras Jim
DN: serialNumber=Z003W8MR, givenName=Jim, sn=Novesteras, o=Siemens, cn=Novesteras Jim
Date: 2019.03.11 01:17:42 -04'00'

Jim Novesteras **Date**
Regulatory Affairs Associate

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA