

## Declaration of Conformity to Directive 98/79/EC

<b>LEGAL MANUFACTURER:</b>	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591-5097, USA
<b>SITE OF MANUFACTURE:</b>	Kimball Electronics Poland Sp z 0.0 ul. Poznanska 1/C tarnowo podgorne Poland 62080
<b>EU AUTHORIZED REPRESENTATIVE</b>	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
<b>NOTIFIED BODY:</b>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
<b>PRODUCTS:</b>	Urinalysis Strips – Self-Test See Table 1 for the complete list of products
<b>CONFORMITY ASSESSMENT ROUTE:</b>	Annex IV of Directive 98/79/EC
<b>CLASSIFICATION:</b>	In Vitro Diagnostic Medical Device for Self-Testing (non-Annex II List A or List B)

### APPLIED STANDARDS:

**EN ISO 13485:2016** – Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes

**EN 13612:2002** – Performance Evaluation of In Vitro 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

Siemens Healthcare Diagnostics Inc.  
Norwood, Massachusetts 02062, USA



**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 18113-4:2011** - In vitro diagnostic medical Devices: Information supplied by the manufacturer (labelling) - In vitro diagnostic reagents for self-testing

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We herewith declare that the below-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, therefore, has fulfilled all requirements for applying the CE mark to the medical devices. The manufacturer retains all supporting documentation.

**Table 1**

SMN	REF (BAN)	Product Code	Product Description
10285741	06916863	2093	CLINITEK MICROALBUMIN 9
10314818	01211267	A2305D29	MULTISTIX 7
10315394	01526748	A2300D18	MULTISTIX 10 SG
10317353	02597428	A2816C51	HEMASTIX
10317384	02614217	A2872C51	ALBUSTIX
10318739	03330964	2083	CLINITEK MICROALBUMIN 2
10318774	03348227	A2872E29	ALBUSTIX
10319565	03783489	A2292C52	MULTISTIX 10 SG
10320335	04200746	A2304C51	MULTISTIX 8 SG
10321054	04624902	A2283J01	MULTISTIX GP
10322217	05258055	A2304D29	MULTISTIX 8 SG
10322360	05328339	A2300A29	MULTISTIX 10 SG
10323903	06184853	A2872C52	ALBUSTIX
10326466	07500392	A2308C29	MULTISTIX 5
10326704	07639781	A2010C34	URITEST 2
10328167	08408406	A2286D34	URITEST

**End of list**

  
 Saurabh Bhatt  
 Regulatory Affairs Specialist

08/13/2020  
 Date