SIEMENS Healthineers

Declaration of Conformity to Directive 98/79/EC

LEGAL MANUFACTURER:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591-5097, USA
SITE 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
NOTIFIED BODY:	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
PRODUCTS:	Urinalysis Strips – Self-Test See Table 1 for the complete list of products
CONFORMITY ASSESSMENT ROUTE:	Annex IV of Directive 98/79/EC
CLASSIFICATION:	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

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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

S Bhatt

Saurabh Bhatt
Regulatory Affairs Specialist

08/13/2020
Date

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