EU DECLARATION OF CONFORMITY

Manufacturer

Name:	*Siemens Healthcare Diagnostics Inc.*
Address:	*511 Benedict Avenue,* *Tarrytown, NY 10591 USA*
Single Registration Number (SRN):	*US-MF-000016560*

Authorized Representative

Name:	*Siemens Healthcare Diagnostics Ltd.*
Address:	*Chapel Lane,* *Swords, Co. Dublin, Ireland*
SRN Authorized Representative:	*IE-AR-000006763*

Manufacturing Facility

Name:	*Kimball Electronics Poland SP z 0.0.*
Address:	*UL.Poznanska 1/C* *Tarnowo Podgorne Poland 62080*

Product Identification See Product Identification Table

We declare that the in vitro diagnostic medical device(s) listed in the Product Identification table is/are in conformity with the following legislation(s):

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

The conformity of the quality management system according to Annex IX and Article 48 is certified by the following notified body:

TÜV Rheinland LGA Products GmbH
Tillystr. 2, 90431 Nürnberg
Germany

The identification number of the notified body for implementation of the procedure set out in Annex IX to the above regulation is:	0197
EU Certificate Technical Documentation Assessment:	IX 1290554-10
EU Certificate Quality Management System:	HX 1290554-1

Reference to Applied Standards:

EN ISO 13485:2016	Quality System for Medical Devices
EN 13612:2002	Performance Evaluation if In-Vitro Medical Devices
EN 13641:2002	Elimination or Reduction of Risk of Infection Related to IVD Reagents

Digitally signed by Marinescu Traian alin
Date: 2025.03.07 14:00:21 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

REPUBLICA MOLDOVA, mun CHIȘINĂU, I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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	IVD Information Supplied by the Manufacturer (Labeling) - Part 1
EN ISO 18113-2:2011	IVD Information Supplied by the Manufacturer (Labeling) - Part 2
EN ISO 23640: 2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

This declaration of conformity is issued under the sole responsibility of *Siemens Healthcare Diagnostics Inc.*
This declaration supersedes any declaration issued previously for the same products.

On Behalf of Siemens Healthcare Diagnostics Inc.:

Place and date: Norwood, MA and May 24, 2024

Signature: *Electronically signed by: Darius Daruwala*
Reason: I am approving this document
Date: May 24, 2024 14:20 EDT

Email: darius.daruwala@siemens-healthineers.com

Signature _____

Name Darius Daruwala
Manager, Regulatory Affairs

Product identification Table

Product/ Trade Name	SMN/REF	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	EMDN Code	EMDN Term	Risk Class	Intended Use
MULTISTIX® 10 SG	10315394	0405686901973WJ	00630414987750	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	The overreaching intended purpose statement for Siemen's urinalysis reagent Strips: Tests performed using the Siemens urinalysis reagent strips are intended for in vitro diagnostic professional use and for self-test. These strips can be read visually (non-automated) and with an instrument (automated). They are intended for the semi-quantitative and/ or qualitative type of measurement of the following in human urine: Albumin, Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Albumin-to-Creatinine Ratio, Specific Gravity, and Urobilinogen. These measurements are used to aid in assessment of conditions such as: • *Kidney disease* • *Urinary tract infections* • *Metabolic disorders (such as diabetes mellitus)* • *Liver disease*
	10322360	0405686901973WJ	00630414602516	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
	10319565	0405686901973WJ	00630414975436	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
Multistix® 8 SG	10320335	0405686901973WJ	00630414984995	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
	10322217	0405686901973WJ	00630414597119	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
Multistix® 7	10314818	0405686901973WJ	00630414987736	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
Multistix® 5	10326466	0405686901973WJ	00630414597126	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
Multistix® GP	10321054	0405686901973WJ	00630414949550	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
Clinistix™ URI Pregnancy Monitoring Urine Test Strips	10328167	0405686901973WJ	00630414948485	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
	11562125		00630414629957						
Clinistix™ URI-2 Urinary Tract Infection Test Strips	10326704	0405686901973WJ	00630414948478	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
	11562123		00630414629643						
	11645051		00630414632179						

Albustix®	10317384	0405686901973WJ	00630414984971	54523	Urine protein IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
	10323903	0405686901973WJ	00630414989075	54523	Urine protein IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
	10318774	0405686901973WJ	00630414602486	54523	Urine protein IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
HEMASTIX®	10317353	0405686901973WJ	00630414984964	54515	Urine blood IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
CLINITEK® Microalbumin 2	10318739	0405686901973WJ	00630414602479	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
CLINITEK® Microalbumin 9	10285741	0405686901973WJ	00630414554907	54514	Multiple urine analyte IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a)	
Clinistix™ HEMA Blood in Urine Test Strips	11643484	0405686901973WJ	00630414629971	54515	Urine blood IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a	
	11645077		00630414632421						
	11645083		00630414632483						
	11645084		00630414632490						
Clinistix™ ALBU Protein in Urine Test Strips	11643489	0405686901973WJ	00630414629988	54523	Urine protein IVD, kit, rapid colorimetric, clinical	W0101	URINE TESTING (CC) - RT & POC	Class C, Rule 4(a	
	11645065		00630414632308						
	11645066		00630414632315						
	11645067		00630414632322						
	11645068		00630414632339						
	11645070		00630414632353						
	11645071		00630414632360						
	11645072		00630414632377						
	11645073		00630414632384						