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 Manufacturing Ltd.*
Address:	*Chapel Lane,* *Swords, Co. Dublin, Ireland*
SRN Authorized Representative:	*IE-AR-000006763*
Manufacturing Facility	
Name:	*Siemens Healthcare Diagnostics Manufacturing Ltd.*
Address:	*Northern Road, Chilton Industrial Estate,* *Sudbury, Suffolk CO10 2XQ, UK*
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 is declared according to Article 48.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Directive 2015/863/EU of 31 March 2015.

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, 17 May 2022*

Darius Daruwala
Manager, Regulatory Affairs

Product Identification Table

Product/ Trade Name	Model	Basic UDI-DI	Risk Class	Intended Purpose
CLINITEK Status®+ Analyzer	10379676 10379677 10379678 10379679 10379680 10379681 10376324	0405686901945WD	**Class A** (According to rule 5(b) Annex VIII In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746)	The CLINITEK Status®+ Urine Chemistry Analyzer is a portable semi-automated, easy to use analyzer. It is designed to read only Siemens Healthcare Diagnostics Reagent Strips for Urinalysis and Clinitest® hCG tests. This analyzer is intended for the semi-quantitative and 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, Urobilinogen, and human Chorionic Gonadotropin (hCG). 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 • Pregnancy Tests performed using the CLINITEK Status®+ analyzer are intended for in vitro diagnostic use only. The CLINITEK Status®+ analyzer is intended for professional use in near patient (point-of-care) facilities and centralized laboratory locations.