

January 12, 2022

DECLARATION OF STANDARDS APPLIED

To whom it may concern,

We, Siemens Healthcare Diagnostics Inc., located at 500 GBC DR, PO Box 6101, Newark, DE 19714, USA as the product owner, hereby declares that the medical devices mentioned in Attachment 1 comply to the below standards.

List of Standards Applied:

Standards Cited in Attachment 1	Standard Name	Current Revision Level
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018	2016/AC:2018
EN 13612	Performance evaluation of in vitro diagnostic medical devices	2002/AC:2002
EN 13640	Stability Testing of in vitro diagnostic reagents	2002
EN 13641	Elimination or reduction of risk of infection related to in vitro diagnostic reagents	2002
EN ISO 14971	Medical Devices- Application of risk management to medical devices (ISO 14971:2007; corrected version 2007-10-01)	2012
EN ISO 15223 – 1	Medical Devices- Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements (ISO 15223-1:2016, Corrected version 2016-12-15)	2016
EN ISO 17511	In vitro diagnostic medical devices- Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)	2003
EN ISO 18113-1	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)	2011
EN ISO 18113-2	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)	2011
EN ISO 18113-3	In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 3: In vitro diagnostic instruments for professional use	2011
EN ISO 23640	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)	2015
EN 62366	Medical Devices – Application of usability engineering to medical devices (IEC 62366:2007)	2008

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IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2015
GHS	Globally Harmonized System of Classification and Labelling of Chemicals (GHS)	2013
EN ISO 18153	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials (ISO 18153:2003)	2003
EN IEC 63000	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	2018

For and on behalf of Siemens Healthcare Diagnostics Inc.

Julie L. Feaster
Regulatory Affairs Specialist

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Product code	Product name	ISO 13485	EN 13612	EN 13640	EN 13641	ISO 14971	ISO 15223-1	EN ISO 17511	EN ISO 18113-1	EN ISO 18113-2	EN ISO 18113-3	EN ISO 23640	IEC 62366	IEC 62366-1	EN ISO 18153	GHS	CTS 2009/108/EC	EN IEC 63000
10445571	Dimension Sample Transfer Module Aliquot Segment	x	x			x	x		x		x		x	x				
10445042	Dimension Cuvette Cartridge	x	x			x	x		x		x		x	x				
10445040	Dimension Small Sample Container (SSC)	x	x			x	x		x		x		x	x				
10481507	Dimension CHK Flex reagent cartridge	x	x	x	x	x	x		x	x		x	x	x		x		
10445039	Dimension Empty Flex reagent cartridge	x	x			x	x		x		x		x	x				
10444887	Dimension Purified Water Diluent	x	x		x	x	x		x	x		x	x	x		x		
10445052	Dimension Chemistry Wash	x	x	x	x	x	x		x		x	x	x	x				
10445036	Dimension Reagent Probe Cleaner	x	x	x	x	x	x		x		x	x	x	x				
10445035	Dimension Sample Probe Cleaner	x	x	x	x	x	x		x		x	x	x	x				
10445038	Dimension IMT Probe Cleaner	x	x	x	x	x	x		x		x	x	x	x				
10444872	QuikLYTE Dilution Check	x	x		x	x	x		x		x	x	x	x		x		
10445051	QuikLYTE Integrated Multisensor Flush Solution	x	x		x	x	x		x		x	x	x	x		x		
10444874	QuikLYTE Integrated Multisensor Sample Diluent	x	x		x	x	x		x		x	x	x	x		x		
10444878	QuikLYTE Integrated Multisensor Standard A	x	x			x	x	x	x		x	x	x	x		x		
10444881	QuikLYTE Integrated Multisensor Standard B	x	x			x	x	x	x		x	x	x	x		x		
10445058	QuikLYTE Integrated Multisensor Na+/K+/Cl-	x	x	x	x	x	x		x		x	x	x					x
10444873	Dimension Salt Bridge Solution	x	x	x	x	x	x		x		x	x	x	x		x		
10464523	Dimension LOCI Free Thyroxine Flex reagent cartridge	x	x	x	x	x	x		x	x		x	x	x		x		
10483414	Dimension LOCI Free Triiodothyronine Flex reagent cartridge	x	x	x	x	x	x		x	x		x	x	x		x		
10464524	Dimension LOCI Thyroid Stimulating Hormone Flex reagent cartridge	x	x	x	x	x	x		x	x		x	x	x		x		

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10484354	Dimension LOCI Thyroid Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10483822	Dimension Hemoglobin A1c Kit	X	X	X	X	X	X	X	X	X		X	X	X		X		
10720883	Dimension Hemoglobin A1c Kit	X	X	X	X	X	X	X	X	X		X	X	X		X		
10459408	Dimension Ethyl Alcohol Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10475530	Dimension Alanine Aminotransferase Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444975	Dimension Albumin Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10642445	Dimension Alkaline Phosphatase Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10711991	Dimension Ammonia Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444965	Dimension Amylase Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444959	Dimension Aspartate Aminotransferase Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10464332	Dimension Automated HDL Cholesterol Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444890	Dimension Automated LDL Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444949	Dimension Calcium Flex reagent cartridge	X	X		X	X	X		X	X		X	X	X		X		
10444891	Dimension Cholesterol Flex reagent cartridge	X	X		X	X	X		X	X		X	X	X		X		
10464511	Dimension Creatine Kinase Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10872079	Dimension Creatinine Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444956	Dimension Direct Bilirubin Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444971	Dimension Glucose Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444945	Dimension Iron Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		

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10284483	Dimension Lactate Dehydrogenase Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444963	Dimension Magnesium Flex reagent cartridge	X	X		X	X	X		X	X		X	X	X		X		
10444977	Dimension Microalbumin Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444964	Dimension Pseudocholesterase Flex reagent cartridge	X	X		X	X	X		X	X		X	X	X		X		
10444957	Dimension Total Bilirubin Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444979	Dimension Total Protein Flex reagent cartridge	X	X		X	X	X		X	X		X	X	X		X		
10444906	Dimension Triglycerides Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444969	Dimension Urea Nitrogen Flex reagent cartridge	X	X		X	X	X		X	X		X	X	X		X		
10444967	Dimension Uric Acid Flex reagent cartridge	X	X		X	X	X		X	X		X	X	X		X		
10444950	Dimension Urinary/Cerebrospinal Fluid Protein Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10444960	Dimension y-Glutamyl Transferase Flex reagent cartridge	X	X		X	X	X		X	X		X	X	X		X		
10444894	Dimension C-Reactive Protein Flex reagent cartridge	X	X		X	X	X		X	X		X	X	X		X		
10444929	Dimension Vancomycin Flex reagent cartridge (VANC)	X	X	X	X	X	X		X	X		X	X	X		X		
10444911	Dimension Thyroid Stimulating Hormone Flex reagent cartridge	X	X	X	X	X	X		X	X		X	X	X		X		
10464328	Dimension AHDLD Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10444996	Dimension ALDL Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10714028	Dimension Alkaline Phosphatase Calibrator	X	X	X	X	X	X		X	X		X	X	X	X	X		
10445013	Dimension Bilirubin Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		

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10716280	Dimension Chemistry I Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10444997	Dimension Chemistry II Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10711580	Dimension Chemistry III Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10444998	Dimension Cholesterol Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10444988	Dimension C-Reactive Protein Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10284680	Dimension Enzyme I Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10476170	Dimension Enzyme II Calibrator	X	X	X	X	X	X		X	X		X	X	X	X	X		
10445016	Dimension Enzyme Verifier	X	X	X	X	X	X		X	X		X	X	X		X		
10445017	Dimension Ferritin Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10445010	Dimension IRON Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10460278	Dimension Lipase Calibrator	X	X	X	X	X	X		X	X		X	X	X	X	X		
10445022	Dimension Microalbumin Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10444987	Dimension Pseudocholinesterase Verifier	X	X	X	X	X	X		X	X		X	X	X		X		
10445018	Dimension Thyroid Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10444993	Dimension Total Protein/Albumin Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10444989	Dimension Urinary/Cerebrospinal Fluid Protein Calibrator (UCFP CAL) cartridge UCFP	X	X	X	X	X	X		X	X		X	X	X		X		
10444870	Dimension Enzyme Diluent	X	X	X	X	X	X		X	X		X	X	X		X		
10444875	Dimension Sample Diluent	X	X	X	X	X	X		X	X		X	X	X		X		

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