

### DECLARATION OF STANDARDS APPLIED

To whom it may concern,

We, **Siemens Healthcare Diagnostics Inc.**, located at 511 Benedict Ave, Tarrytown, NY 10591, 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	2011

	the manufacturer (labelling) -- Part 3: In vitro diagnostic instruments for professional use	
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
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
CTS 2009/108/EC	Commission Decision of 3 February 2009 amending Decision 2002/364/EC on common technical specifications for in vitro-diagnostic medical devices	N/A
EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	2012

For and on behalf of Siemens Healthcare Diagnostics Inc.

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Dawn Fallon  
Regulatory Affairs Specialist



**Attachment 1**

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	EN 50581	CTS 2009/108/EC
10718754	ADVIA Chemistry XPT ISE Buffer 2 (ISE Buf2)	X	X	X	X	X	X	X		X	X	X	X		X			
10718755	ADVIA Chemistry XPT ISE Baseline Solution (ISE BSol)	X	X	X	X	X	X	X		X	X	X	X		X			
10718753	ADVIA Chemistry XPT Cuvette Detergent	X	X	X	X	X	X	X		X	X	X	X		X			
10718756	ADVIA Chemistry XPT Probe Wash 0	X	X	X	X	X	X	X	X		X	X	X		X			
10309450	ADVIA Chemistry Systems Sample Cup	X	X			X	X	X		X		X	X					
10311853	ADVIA Chemistry Cuvette Wash Solution	X	X	X	X	X	X	X		X	X	X	X		X			
10311854	ADVIA Chemistry Cuvette Conditioner	X	X	X	X	X	X	X		X	X	X	X		X			
10311856	ADVIA Chemistry Reagent Probe Wash 1	X	X	X	X	X	X	X		X	X	X	X		X			
10311857	ADVIA Chemistry Reagent Probe Wash 2	X	X	X	X	X	X	X		X	X	X	X		X			
10311858	ADVIA Chemistry Reagent Probe Wash 3	X	X	X	X	X	X	X		X	X	X	X		X			
10487137	ADVIA Chemistry Systems 20-mL Reagent Wedge	X	X			X	X	X		X		X	X		X			
10487142	ADVIA Chemistry Systems 40-mL Reagent Wedge	X	X			X	X	X		X		X	X		X			

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10487138	ADVIA Chemistry Systems 70-mL Reagent Wedge (Clear)	X	X			X	X		X		X		X	X		X		
10720857	ADVIA Chemistry Enzymatic Hemoglobin A1c (A1c_E) Assay	X	X	X	X	X	X		X	X		X	X	X		X		
10720858	ADVIA Chemistry Enzymatic Hemoglobin A1c (A1c_E) Assay	X	X	X	X	X	X	X	X	X		X	X	X		X		
10361941	ADVIA Chemistry Fructosamine Reagent (FRUC)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10327381	ADVIA Chemistry Acetaminophen Reagents (ACET)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10379635	ADVIA Chemistry Ethanol_2 Reagents (ETOH_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309500	ADVIA Chemistry Alanine Aminotransferase Reagents (ALT)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10318168	ADVIA Chemistry Alanine Aminotransferase Reagents (ALT)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309496	ADVIA Chemistry Aspartate Aminotransferase Reagents (AST)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10341132	ADVIA Chemistry Aspartate Aminotransferase Reagents (AST)	X	X	X	X	X	X	X	X	X		X	X	X		X		

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10311832	ADVIA Chemistry Albumin Reagent (ALB)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10711840	DVIA Chemistry Albumin BCP Reagents (ALBP)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10916067	ADVIA Chemistry Alkaline Phosphatase_2 Concentrated Reagents (ALP_2c)	X	X	X	X	X	X		X	X		X	X	X	X	X		
10286035	ADVIA Chemistry Ammonia Reagents (AMM)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309493	ADVIA Chemistry Amylase Reagents (AMYLAS)	X	X	X	X	X	X		X	X		X	X	X	X	X		
10341130	ADVIA Chemistry Amylase Reagents (AMYLAS)	X	X	X	X	X	X		X	X		X	X	X	X	X		
10316610	ADVIA Chemistry Direct Bilirubin_2 Reagents (DBIL_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10341114	ADVIA Chemistry Direct Bilirubin_2 Reagents (DBIL_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10341113	ADVIA Chemistry Total Bilirubin_2 Reagents (TBIL_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10286036	Advia Chemistry Calcium Reagents (CA)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10341116	Advia Chemistry Calcium_2 Reagents (CA_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10316612	Advia Chemistry Calcium_2 Reagents (CA_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		

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10720780	ADVIA Chemistry Carbon Dioxide Concentrated Reagent (CO2_c)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10283345	ADVIA Chemistry Carbon Dioxide Concentrated Reagent (CO2_c)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10376501	ADVIA Chemistry Cholesterol_2 Reagent (CHOL_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10315176	ADVIA Chemistry Cholinesterase Reagents (CHE)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10729780	ADVIA Chemistry Creatine Kinase Assay (CK_L)	X	X	X	X	X	X		X	X		X	X	X	X	X		
10309050	ADVIA Chemistry Creatinine (CREA / CREA_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10335869	ADVIA Chemistry Enzymatic Creatinine_2 Reagents (ECRE_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309495, 10316298	ADVIA Chemistry Gamma-Glutamyl Transferase Reagents (GGT)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10492319	ADVIA Chemistry Glucose Oxidase Reagents (GLUO)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10335891	ADVIA Chemistry Glucose Hexokinase_3 Reagents (GLUH_3)	X	X	X	X	X	X	X	X	X		X	X	X		X		

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10377502	Advia Chemistry Glucose Hexokinase_3 reagents, Concentrated (GLUH_c)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10283089	ADVIA Chemistry Direct HDL Cholesterol Reagents (D-HDL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10341118; 10377510	ADVIA Chemistry Iron_2 Reagents (IRON_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10325776	ADVIA Chemistry Lactate Reagents (LAC)	X	X	X	X	X	X		X	X		X	X	X	X	X		
10309501, 10341128	ADVIA Chemistry Lactate Dehydrogenase L-P Reagents (LDLP)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10341129	ADVIA Chemistry Lactate Dehydrogenase P-L Reagents (LDPL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10311891	ADVIA Chemistry Direct LDL Cholesterol Reagents (DLDL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10311896	ADVIA Chemistry Lipase Reagents (LIP)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309506, 10341119	Advia Chemistry Magnesium Reagents (MG)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10318197	ADVIA Chemistry Microalbumin_2 Reagents (μALB_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		

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10315178	ADVIA Chemistry Pancreatic Amylase Reagents (PAMY)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309503, 10318211	Advia Chemistry Inorganic Phosphorus Reagents (IP)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309071	ADVIA Chemistry Total Iron Binding Capacity Reagents (TIBC)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10311878	ADVIA Chemistry Total Protein II Reagents (TP)	X	X	X	X	X	X	X	X	X		X	X	X		X		
11319151	Advia Chemistry Urinary/Cerebrospinal Fluid Protein (UCFP)	X	X	X	X	X	X		X	X		X	X	X				
10335892	ADVIA Chemistry Triglycerides_2 Reagents (TRIG_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309051	ADVIA Chemistry Urea Nitrogen Reagents (UN)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309492, 10341133	ADVIA Chemistry Uric Acid Reagents (UA)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10361936	ADVIA Chemistry $\alpha$ 1-Acid Glycoprotein Reagents (AAG)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10318221	ADVIA Chemistry $\alpha$ 1-Antitrysin Reagents (AAT)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10318208	ADVIA Chemistry Anti-Streptolysin-O_2 Reagents (ASO_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		



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10361937	ADVIA Chemistry $\beta$ 2-Microglobulin Reagents (B2M)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309053	ADVIA Chemistry Complement C3 Reagents (C3) Reagents	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309054	ADVIA Chemistry Complement C4 Reagents (C4) Reagents	X	X	X	X	X	X	X	X	X		X	X	X		X		
10283129	ADVIA Chemistry C-Reactive Protein_2 Reagents (CRP_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10341101	ADVIA Chemistry Wide Range C-Reactive Protein Reagents (wrCRP)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10734503	ADVIA Chemistry Cystatin C_2 Reagents (CYSC_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10361930	ADVIA Chemistry Cystatin C Reagents (CYSC)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10361938	ADVIA Chemistry Ferritin Reagents (FRT)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10323850	ADVIA Chemistry Haptoglobin Reagents (HAPT)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309033	ADVIA Chemistry Immunoglobulin A_2 Reagents (IGA_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10309031	ADVIA Chemistry Immunoglobulin G_2 Reagents (IGG_2)	X	X	X	X	X	X	X	X	X		X	X	X		X		

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10309032	ADVIA Chemistry Immunoglobulin M_2 Reagents (IGM_2)	x	x	x	x	x	x	x	x	x		x	x	x		x		
10361942	ADVIA Chemistry Lipoprotein(a) Reagents (LPA)	x	x	x	x	x	x	x	x	x		x	x	x		x		
10318214	ADVIA Chemistry Prealbumin Reagents (PREALB)	x	x	x	x	x	x	x	x	x		x	x	x		x		
10311894	ADVIA Chemistry Rheumatoid Factor Reagents (RF)	x	x	x	x	x	x	x	x	x		x	x	x		x		
10318218	ADVIA Chemistry Transferrin Reagents (TRF)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11532400	ADVIA Chemistry Lithium_2 (LITH_2)	x	x		x	x	x		x	x		x	x			x		x
10377509	ADVIA Chemistry Vancomycin_2 Reagents (VANC_2)	x	x	x	x	x	x	x	x	x		x	x	x		x		
10311849	ADVIA Chemistry ISE Buffer	x	x	x	x	x	x		x		x	x	x	x	x	x		
10321715	ADVIA Chemistry ISE Buffer	x	x	x	x	x	x		x		x	x	x	x	x	x		
10311851	ADVIA Chemistry ISE Detergent Solution	x	x	x	x	x	x		x		x	x	x	x	x	x		
10311903	ADVIA Chemistry ISE Serum Standard Set	x	x	x	x	x	x	x	x	x		x	x	x		x		
10311904	ADVIA Chemistry ISE Urine Standard Set	x	x	x	x	x	x	x	x	x		x	x	x		x		
10309439	ADVIA Chemistry Chloride Electrode (Cl-)	x	x		x	x	x	x	x	x		x	x				x	

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10309440	ADVIA Chemistry Potassium Electrode (K+)	X	X		X	X	X	X	X	X		X	X				X	
10309441	ADVIA Chemistry Sodium Electrode (Na+)	X	X		X	X	X	X	X	X		X	X				X	
10309465	ADVIA Chemistry Reference Electrode (Ref.)	X	X		X	X	X	X	X	X		X	X				X	
10720859	ADVIA Chemistry Enzymatic Hemoglobin A1c Calibrator (A1c_E Cal)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10711842	ADVIA Chemistry Albumin BCP Calibrator (ALBP CAL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10916057	ADVIA Chemistry Enzyme 1 Calibrator (ENZ 1 CAL)	X	X	X	X	X	X	X	X	X		X	X	X	X	X		
10916058	ADVIA Chemistry Enzyme 2 Calibrator (ENZ 2 CAL)	X	X	X	X	X	X	X	X	X		X	X	X	X	X		
10309217	Advia Chemistry ToxAmmonia Calibrators (ToxAmmonia CAL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10916060	ADVIA Chemistry Alkaline Phosphatase_2 Calibrator (ALP_2 CAL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10311898	ADVIA Chemistry Apolipoprotein A1/B Calibrator (APO A1/B CAL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10285680	ADVIA Chemistry $\beta$ 2-Microglobulin Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		

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10326423	Advia Chemistry CO2 Calibrator/Diluent	X	X	X	X	X	X	X	X	X		X	X	X		X		
10337471	ADVIA Chemistry C-Reactive Protein_2 Calibrators (CRP_2 CAL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10734510	ADVIA Chemistry Cystatin C_2 Calibrators (CYSC_2 CAL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10376487	ADVIA Chemistry Cystatin C Calibrators (CYSC CAL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10285684	ADVIA Chemistry Fructosamine Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10311918	ADVIA Chemistry HDL/LDL Cholesterol Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10285017	ADVIA Chemistry Lipoprotein(a) Calibrator (LPA) CAL	X	X	X	X	X	X	X	X	X		X	X	X		X		
10311929	Advia Chemistry Liquid Specific Protein Calibrators (LSP CAL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10337470	ADVIA Chemistry MicroAlbumin_2 Calibrator (MALB_2 CAL)	X	X	X	X	X	X	X	X	X		X	X	X		X		
10312279	Advia Chemistry Chemistry Calibrator	X	X	X	X	X	X	X	X	X		X	X	X		X		
10311926	Advia Chemistry Special Chemistry Calibrator (SPCL CHEM CAL)	X	X	X	X	X	X	X	X	X		X	X	X		X		

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11319152	Advia Chemistry Urinary/Cerebrospinal Fluid Protein Calibrator (UCFP CAL)	X	X	X	X	X	X	X	X	X		X	X	X	X	X		
10313256	ADVIA Chemistry Wide Range C-Reactive Protein Calibrator (wrCRP CAL)	X	X	X	X	X	X		X	X		X	X	X		X		
10916059	ADVIA Chemistry Enzyme 3 Calibrator (ENZ 3 CAL)	X	X	X	X	X	X		X	X		X	X	X	X	X		