

## 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 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
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 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.

---

Elena Camposano  
Regulatory Affairs Specialist



**Attachment 1**

Standards		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
Product code	Product name																	
11097637	Atellica CH Fructosamine (Fruc)	x	x	x	x	x	x		x	x		x	x	x		x		
11097536	Atellica CH Enzymatic Hemoglobin A1c (A1c_E)	x	x		x	x	x	x	x	x		x	x					
11097522	Atellica CH Acetaminophen (Acet)	x	x	x	x	x	x		x	x		x	x	x		x		
11097506	Atellica CH Amphetamines (Amp)	x	x	x	x	x	x		x	x		x	x	x		x		
11097505	Atellica CH Benzodiazepines (Bnz)	x	x	x	x	x	x		x	x		x	x	x		x		
11097507	Atellica CH Barbiturates (Brb)	x	x	x	x	x	x		x	x		x	x	x		x		
11097504	Atellica CH Cocaine Metabolite (Coc)	x	x	x	x	x	x		x	x		x	x	x		x		
11097501	Atellica CH Ethyl Alcohol (ETOH)	x	x	x	x	x	x		x	x		x	x	x		x		
11097520	Atellica CH Methadone (Mdn)	x	x	x	x	x	x		x	x		x	x	x		x		
11097502	Atellica CH Opiates (Op)	x	x	x	x	x	x		x	x		x	x	x		x		
11097509	Atellica CH Phencyclidine (Pcp)	x	x	x	x	x	x		x	x		x	x	x		x		
11097519	Atellica CH Propoxyphene (Ppx)	x	x	x	x	x	x		x	x		x	x	x		x		
11097523	Atellica CH Salicylate (Sal)	x	x	x	x	x	x		x	x		x	x	x		x		
11097503	Atellica CH Cannabinoids THC (Thc)	x	x	x	x	x	x		x	x		x	x	x		x		
11097518	Atellica CH Ecstasy (Xtc)	x	x	x	x	x	x		x	x		x	x	x		x		
11097605	Atellica CH Alanine Aminotransferase (ALT)	x	x	x	x	x	x		x	x		x	x	x		x		
11097590	Atellica CH Albumin (Alb)	x	x	x	x	x	x		x	x		x	x	x		x		
11097530	Atellica CH Albumin BCP (AlbP)	x	x	x	x	x	x		x	x		x	x	x		x		
11097600	Atellica CH Alkaline Phosphatase, Concentrated (ALP_2c)	x	x	x	x	x	x		x	x		x	x	x		x		

Standards		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
11097629	Atellica CH Alpha-1-acid Glycoprotein (AAG)	x	x	x	x	x	x		x	x		x	x	x		x		
11097603	Atellica CH Amylase (Amylas)	x	x	x	x	x	x		x	x		x	x	x		x		
11097649	Atellica CH Amylase_2 (AMY_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097607	Atellica CH Aspartate Aminotransferase (AST)	x	x	x	x	x	x		x	x		x	x	x		x		
11097639	Atellica CH Aspartate Aminotransferase P5P (ASTPLc)	x	x	x	x	x	x		x	x		x	x	x		x		
11097595	Atellica CH Calcium (Ca)	x	x	x	x	x	x		x	x		x	x	x		x		
11097644	Atellica CH Calcium_2 (Ca_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097521	Atellica CH Carbon Dioxide, Concentrated (CO2_c)	x	x	x	x	x	x		x	x		x	x	x		x		
11097609	Atellica CH Cholesterol_2 (Chol_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097615	Atellica CH Cholinesterase (CHE)	x	x	x	x	x	x		x	x		x	x	x		x		
11097640	Atellica CH Creatine Kinase (CK_L)	x	x	x	x	x	x		x	x		x	x	x		x		
11097596	Atellica CH Creatinine_2 (Crea_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097532	Atellica CH Direct Bilirubin 2 (DBil_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097630	Atellica CH Direct HDL Cholesterol (D-HDL)	x	x	x	x	x	x		x	x		x	x	x		x		
11537213	Atellica CH HDLC	x	x		x	x	x		x	x		x	x			x	x	
11097533	Atellica CH Enzymatic Creatinine_2 (ECre_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097597	Atellica CH Gamma-Glutamyl Transferase (GGT)	x	x	x	x	x	x		x	x		x	x	x		x		

Standards		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
11097592	Atellica CH Glucose Hexokinase_3 (GluH_3)	x	x	x	x	x	x		x	x		x	x	x		x		
11097621	Atellica CH Glucose Oxidase (GluO)	x	x	x	x	x	x		x	x		x	x	x		x		
11097611	Atellica CH Inorganic Phosphorus (IP)	x	x	x	x	x	x		x	x		x	x	x		x		
11097601	Atellica CH Iron_2 (Iron_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097614	Atellica CH Lactate (Lac)	x	x	x	x	x	x		x	x		x	x	x		x		
11532568	Atellica CH Lactate_2 (Lac_2)	x	x		x	x	x		x	x		x	x			x		
11097594	Atellica CH Lactate Dehydrogenase L-P (LDLP)	x	x	x	x	x	x		x	x		x	x	x		x		
11097632	Atellica CH LDL Cholesterol Direct (DLDL)	x	x	x	x	x	x		x	x		x	x	x		x		
11537214	Atellica CH LDLC	x	x		x	x	x		x	x		x	x			x	x	
11097606	Atellica CH Lipase (Lip)	x	x	x	x	x	x		x	x		x	x	x		x		
11097612	Atellica CH Magnesium (Mg)	x	x	x	x	x	x		x	x		x	x	x		x		
11097610	Atellica CH Microalbumin_2 (μALB_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097579	Atellica CH Pancreatic Amylase_2 (PAMY_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097531	Atellica CH Total Bilirubin_2 (TBil_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097525	Atellica CH Total Iron Binding Capacity (TIBC)	x	x	x	x	x	x		x	x		x	x	x		x		
11097604	Atellica CH Total Protein II (TP)	x	x	x	x	x	x		x	x		x	x	x		x		
11097591	Atellica CH Triglycerides (concentrated) (Trig)	x	x	x	x	x	x		x	x		x	x	x		x		

Standards		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
11537222	Atellica CH Trig_2	x	x		x	x	x		x								x	
11097593	Atellica CH Urea Nitrogen (UN_c)	x	x	x	x	x	x		x	x		x	x	x		x		
11097608	Atellica CH Uric Acid (UA)	x	x	x	x	x	x		x	x		x	x	x		x		
11097543	Atellica CH UCFP	x	x	x	x	x	x		x	x		x	x	x		x		
11097628	Atellica CH Alpha-1-antitrypsin (AAT)	x	x	x	x	x	x		x	x		x	x	x		x		
11097625	Atellica CH Apolipoprotein A-1 (APO A1)	x	x	x	x	x	x		x	x		x	x	x		x		
11097626	Atellica CH Apolipoprotein B (APO B)	x	x	x	x	x	x		x	x		x	x	x		x		
11097634	Atellica CH Anti-Streptolysin-O_2 (ASO_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097624	Atellica CH Complement C3 (C3)	x	x	x	x	x	x		x	x		x	x	x		x		
11097623	Atellica CH Complement C4 (C4)	x	x	x	x	x	x		x	x		x	x	x		x		
11097631	Atellica CH C-Reactive Protein_2 (CRP_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097647	Atellica CH Cystatin C_2 (CYSC_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097643	Atellica CH Haptoglobin (Hapt)	x	x	x	x	x	x		x	x		x	x	x		x		
11097619	Atellica CH Immunoglobulin A_2 (IgA_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097616	Atellica CH Immunoglobulin G_2 (IgG_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097620	Atellica CH Immunoglobulin M_2 (IgM_2)	x	x	x	x	x	x		x	x		x	x	x		x		
11097627	Atellica CH Lipoprotein(a) (Lp(a))	x	x	x	x	x	x		x	x		x	x	x		x		

Standards		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
11097617	Atellica CH Prealbumin (PreAlb)	x	x	x	x	x	x		x	x		x	x	x		x		
11097618	Atellica CH Rheumatoid Factor (RF)	x	x	x	x	x	x		x	x		x	x	x		x		
11097613	Atellica CH Transferrin (Trf)	x	x	x	x	x	x		x	x		x	x	x		x		
11097635	Atellica CH $\beta$ 2-Microglobulin (B2M)	x	x	x	x	x	x		x	x		x	x	x		x		
11097645	Atellica CH Wide Range C-Reactive Protein (wrCRP)	x	x	x	x	x	x		x	x		x	x	x		x		
11097535	Atellica CH Lithium (Li)	x	x	x	x	x	x		x	x		x	x	x		x		
11532401	Atellica CH Lithium_2 (Lith_2)	x	x		x	x	x		x	x		x	x			x	x	
11097539	Atellica CH Lidocaine (LIDO)	x	x	x	x	x	x		x	x		x	x	x		x		
11097537	Atellica CH N-Acetylprocainamide (NPA)	x	x	x	x	x	x		x	x		x	x	x		x		
11097541	Atellica CH Oxycodone (OXY)	x	x	x	x	x	x		x	x		x	x	x		x		
11097510	Atellica CH Phenytoin (Phny)	x	x	x	x	x	x		x	x		x	x	x		x		
11097538	Atellica CH Procainamide (PROC)	x	x	x	x	x	x		x	x		x	x	x		x		
11097513	Atellica CH Theophylline (Theo)	x	x	x	x	x	x		x	x		x	x	x		x		
11097517	Atellica CH Tobramycin (Tob)	x	x	x	x	x	x		x	x		x	x	x		x		
11097512	Atellica CH Valproic Acid (VPA)	x	x	x	x	x	x		x	x		x	x	x		x		
11097511	Atellica CH Vancomycin (Vanc)	x	x	x	x	x	x		x	x		x	x	x		x		
11099315	A-LYTE Integrated Multisensor (IMT Na K Cl)	x	x	x	x	x	x		x	x		x	x	x		x		x
11099304	A-LYTE IMT Standard A	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099306	A-LYTE IMT Standard B + Salt Bridge	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099406	Atellica CH Multi-Drug Urine Controls (MULTIDRUG QC)	x	x	x	x	x	x		x	x		x	x	x		x		

Standards		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
11099338	Atellica CH A1c_E CAL	x	x		x	x	x	x	x	x		x	x					
11099310	Atellica CH Albumin BCP Calibrator (AlbP CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099316	Atellica CH Alkaline Phosphatase_2 Calibrator (ALP_2 CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099329	Atellica CH Apolipoprotein A-1 & B Calibrator (APO A1 & B CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099335	Atellica CH CHEM III Calibrator (CHEM III CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099411	Atellica CH Chemistry Calibrator (CHEM CAL)	x	x		x	x	x	x	x	x		x	x	x		x		
11099401	Atellica CH CO2 Calibrator/Diluent	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099430	Atellica CH C-Reactive Protein_2 Calibrators (CRP_2 CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11097648	Atellica CH Cystatin C_2 Calibrators (CYSC_2 CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099317	Atellica CH ENZ 1 Calibrator (ENZ 1 CAL)	x	x	x	x	x	x	x	x	x		x	x	x	x	x		
11099318	Atellica CH ENZ 2 Calibrator (ENZ 2 CAL)	x	x	x	x	x	x	x	x	x		x	x	x	x	x		
11099319	Atellica CH ENZ 3 Calibrator (ENZ 3 CAL)	x	x	x	x	x	x	x	x	x		x	x	x	x	x		
11099432	Atellica CH Fructosamine Calibrator	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099402	Atellica CH HDL/LDL Cholesterol Calibrator (HDL/LDL CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099433	Atellica CH Lipoprotein(a) Calibrator (Lp(a) CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		



Standards		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
11099434	Atellica CH Liquid Specific Protein Calibrators (LSP CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099437	Atellica CH Methadone Metabolite 1000 ng/mL Urine Calibrator (MetMtb CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099435	Atellica CH Microalbumin_2 Calibrator (μALB_2 CAL)	x	x		x	x	x	x	x	x		x	x	x		x		
11099438	Atellica CH Special Chemistry Calibrator (SPCL CHEM CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099440	Atellica CH Toxicology Calibrator (TOX CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099441	Atellica CH Total Protein Urine Calibrator (UPro CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11097646	Atellica CH Wide Range C-Reactive Protein Calibrators (wrCRP CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099442	Atellica CH β <sub>2</sub> -Microglobulin Calibrator (B2M CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11099339	Atellica CH Urinary/Cerebrospinal Fluid Protein Calibrators (UCFP CAL)	x	x	x	x	x	x	x	x	x		x	x	x		x		
11537241	Atellica CH LDLC CAL	x	x		x	x	x	x	x	x		x	x			x	x	
11537240	Atellica CH HDLC CAL	x	x		x	x	x	x	x	x		x	x			x	x	
11099305	A-LYTE IMT Diluent	x	x	x	x	x	x		x	x		x	x	x		x		
11099300	Atellica CH Diluent	x	x	x	x	x	x		x	x		x	x	x		x		

Standards		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
11099301	Atellica CH Wash	x	x	x	x	x	x		x	x		x	x	x		x		
11099302	Atellica CH Conditioner	x	x	x	x	x	x		x	x		x	x	x		x		
11099303	Atellica CH Cleaner	x	x	x	x	x	x		x	x		x	x	x		x		
11099311	Atellica CH Check Reagent (CHK)	x	x	x	x	x	x		x	x		x	x	x		x		
11099312	Atellica CH Reagent Probe Cleaner 1 (RPC1)	x	x	x	x	x	x		x	x		x	x	x		x		
11099313	Atellica CH Reagent Probe Cleaner 2 (RPC2)	x	x	x	x	x	x		x	x		x	x	x		x		
11099309	Atellica CH Reagent Probe Cleaner 4 (RPC4)	x	x	x	x	x	x		x	x		x	x	x		x		
11099307	Atellica CH Lamp Coolant (LC)	x	x	x	x	x	x		x	x		x	x	x		x		
11099308	Atellica CH Water Bath Additive (WBA)	x	x	x	x	x	x		x	x		x	x	x		x		
11099327	Atellica CH Dilution Ring Segment	x	x			x	x		x		x		x	x				
11099326	Atellica CH Reaction Ring Segment	x	x			x	x		x		x		x	x				
11538114	Atellica CH EMPTY1	x	x			x	x		x		x		x					
11538115	Atellica CH EMPTY2	x	x			x	x		x		x		x					
11099325	A-LYTE IMT Dilution Check	x	x	x	x	x	x		x	x		x	x	x		x		