



Siemens Healthcare Diagnostics Inc.
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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:

- | | |
|----------------------------------|--|
| EN ISO 13485:2016/AC:2018 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) |
| EN 13612:2002/AC:2002 | Performance evaluation of in vitro diagnostic medical devices |
| EN 13641:2002 | Elimination or reduction of risk of infection related to in vitro diagnostic reagents |

For and on behalf of
Siemens Healthcare Diagnostics Inc.

Elena Camposano
Regulatory Affairs Specialist

Attachment 1

Siemens Material Number	Part Number	Product Description
10995540	10995540	Atellica IM Cortisol Urine Reconstitution Buffer
10995463	10995463	Atellica IM Anti-Thyroglobulin Diluent (aTG DIL)
10995468	10995468	Atellica IM Anti-Thyroid Peroxidase Diluent (aTPO DIL)
10995491	10995491	Atellica IM CA 19-9 Diluent (CA 19-9 DIL)
10995525	10995525	Atellica IM Carcinoembryonic Antigen Diluent (CEA DIL)
10995533	10995533	Atellica IM Creatine Kinase MB Diluent (CKMB DIL)
10995563	10995563	Atellica IM Enhanced Estradiol Diluent (eE2 DIL)
10995574	10995574	Atellica IM Folate Diluent (Fol DIL)
10995608	10995608	Atellica IM Homocysteine Diluent (HCY DIL)
10995616	10995616	Atellica IM Total IgE Diluent (tIgE DIL)
10995630	10995630	Atellica IM Insulin Diluent (IRI DIL)
10995631	10995631	Atellica IM Insulin Diluent (IRI DIL)
10995680	10995680	Atellica IM Total Triiodothyronine Diluent (T3 DIL)
10995686	10995686	Atellica IM Total Thyroxine Diluent (T4 DIL)
10995691	10995691	Atellica IM Total hCG Diluent (ThCG DIL)
10995692	10995692	Atellica IM Total hCG Diluent (ThCG DIL)
10995693	10995693	Atellica IM Total hCG Diluent (ThCG DIL)
10995716	10995716	Atellica IM Vitamin B12 Diluent (VB12 DIL)
10995721	10995721	Atellica IM Vitamin D Diluent (VitD DIL)
10995440	10995440	Atellica IM RBC Folate Ascorbic Acid / Ascorbic Acid Diluent (RBC Fol)
10995480	10995480	Atellica IM BR 27.29 Pretreatment Reagent (BR PRE)
10995546	10995546	Atellica IM cPSA Pretreatment Reagent (cPSA PRE)
10995552	10995552	Atellica IM Cyclosporine Pretreatment Reagent (CsA PRE)
10995576	10995576	Atellica IM Folate DTT/Releasing Agent (Fol DTT/REL)
10995718	10995718	Atellica IM Vitamin B12 DTT/ Releasing Agent
11208098	11208098	COV2Ag Sample Lysis Reagent
11208651	11208651	Sample Inactivation Media
10995493	10995493	Atellica IM Calibrator 1 (CAL 1)
10995495	10995495	Atellica IM Calibrator 30 (CAL 30)
10995496	10995496	Atellica IM Calibrator 30 (CAL 30)
10995497	10995497	Atellica IM Calibrator 80 (CAL 80)

Siemens Material Number	Part Number	Product Description
10995500	10995500	Atellica IM Calibrator A (CAL A)
10995501	10995501	Atellica IM Calibrator A (CAL A)
10995506	10995506	Atellica IM Calibrator C (CAL C)
10995507	10995507	Atellica IM Calibrator C (CAL C)
10995512	10995512	Atellica IM Calibrator E (CAL E)
10995513	10995513	Atellica IM Calibrator E (CAL E)
10995516	10995516	Atellica IM Calibrator O (CAL O)
10995542	10995542	Atellica IM C-peptide Calibrator (CpS CAL)
10995565	10995565	Atellica IM Enhanced Liver Fibrosis Calibrator (ELF CAL)
10995498	10995498	Atellica IM Homocysteine Calibrator (HCY CAL)
10995629	10995629	Atellica IM Insulin Calibrator (IRI CAL)
10995673	10995673	Atellica IM Sex Hormone Binding Globulin Calibrator (SHBG CAL)
10733002	10733002	Atellica IM Active-B12 Quality Control (AB12 QC)
10732999	10732999	Atellica IM Anti-CCP IgG Quality Control (aCCP QC)
10733008	10733008	Atellica IM Erythropoietin Quality Control (EPO QC)
10995465	10995465	Atellica IM Anti-Thyroglobulin Quality Control (aTG QC)
11201752	11201752	Atellica IM Anti-Thyroglobulin II Quality Control (aTgII QC)
10995470	10995470	Atellica IM Anti-Thyroid Peroxidase Quality Control (aTPO QC)
10995566	10995566	Atellica IM Enhanced Liver Fibrosis Quality Control (ELF™ QC)
10733014	10733014	Atellica IM Interleukin-6 Quality Control (IL6 QC)
10733018	10733018	Atellica IM Lipopolysaccharide Binding Protein Quality Control (LBP QC)
10995626	10995626	Atellica IM Intact Parathyroid Hormone Quality Control (PTH QC)
10995724	10995724	Atellica IM Vitamin D Total Quality Control (VitD QC)
10309951	04542396	ADVIA Centaur CKMB Diluent (2PK)
10491878	10491878	ADVIA Centaur eE2 Diluent (2PK)
10310389	07824546	ADVIA Centaur FOL Diluent (2PK)
10310462	05080264	ADVIA Centaur IRI Diluent (2PK)
10310279	05609230	ADVIA Centaur ThCG Diluent (2PK)
10323214	05794569	ADVIA Centaur ThCG Diluent (6PK)
10309949	02531958	ADVIA Centaur VB12 Diluent (2PK)
10309999	03479704	ADVIA Centaur Multi-Diluent 11
10316877	02343590	ADVIA Centaur FOL Ascorbic Acid (lypholized) / Ascorbic Acid Diluent
10310463	01043186	ADVIA Centaur IRI Diluent

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10310213	05111259	ADVIA Centaur ThCG Diluent
10335453	04567127	ADVIA Centaur CsA Pretreatment reagent
10310382	05171359	ADVIA Centaur FOL DTT/Releasing Agent (600 tests)
10310330	03536015	ADVIA Centaur VB12 DTT/Releasing Agent
10318246	03071551	Cortisol Urine Reconstitution Buffer
10630915	10630915	ADVIA Centaur Calibrator 1
10310432	08501406	ADVIA Centaur Calibrator 27
10322222	05259132	ADVIA Centaur Calibrator 28
10379810	10379810	ADVIA Centaur Calibrator 30
10379811	10379811	ADVIA Centaur Calibrator 30
10492491	10492491	ADVIA Centaur Calibrator 80
10285903	04800646	ADVIA Centaur Calibrator A
10285904	04800735	ADVIA Centaur Calibrator A
10311568	03439230	ADVIA Centaur Calibrator C
10311575	06567787	ADVIA Centaur Calibrator C
10309079	04634452	ADVIA Centaur Calibrator E
10321075	04634762	ADVIA Centaur Calibrator E
10630932	10630932	ADVIA Centaur Calibrator O
10310445	03276056	ADVIA Centaur C-peptide Calibrator
10492344	10492344	ADVIA Centaur ELF Calibrator
10310376	05530553	ADVIA Centaur HCY Calibrator
10310438	04618899	ADVIA Centaur Insulin Calibrator
10997192	10997192	ADVIA Centaur SHBG Calibrator
10995091	10995091	ADVIA Centaur Active-B12 (AB12) Quality Control
10630917	10630917	ADVIA Centaur anti-Tg 1,2 Quality Control
11202552	11202552	ADVIA Centaur aTgII Quality Control (aTgII QC)
10630936	10630936	ADVIA Centaur anti-TPO 1,2 Quality Control
10492342	10492342	ADVIA Centaur ELF Quality Control
10995099	10995099	ADVIA Centaur EPO Quality Control Material
10699156	10699156	ADVIA Centaur Intact Parathyroid Hormone (PTH) Quality Control
10995083	10995083	ADVIA Centaur Interleukin-6 (IL6) Quality Control
10995087	10995087	ADVIA Centaur Lipopolysaccharide Binding Protein (LBP) Quality Control
10699200	10699200	ADVIA Centaur Vitamin D Total (VitD) Quality Control