



Siemens Healthcare Diagnostics Inc.
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Date: January 25, 2022

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
- EN ISO 14971:2012** Medical devices – Application of risk management to medical devices (ISO 14971:2007)
- EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016, Corrected version 2016-12-15)
- EN ISO 17511:2003** In vitro diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)
- EN ISO 18113-1:2011** In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)

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| EN ISO 18113-2:2011 | In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009) |
| EN ISO 23640:2015 | In vitro diagnostic medical devices -- Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011) |
| EN 62366:2008 | Medical devices -- Application of usability engineering to medical devices (IEC 62366:2007/A1:2014) |

For and on behalf of
Siemens Healthcare Diagnostics Inc.

Elena Camposano
Regulatory Affairs Specialist

Attachment 1

Siemens Material Number	Part Number	Product Description
11208299	11208299	Atellica IM sCOVG Diluent
10995615	10995615	Atellica IM Total IgE (tIgE)
10995614	10995614	Atellica IM Total IgE (tIgE)
10733001	10733001	Atellica IM Active-B12 (Holotranscobalamin) (AB12)
10733006	10733006	Atellica IM Erythropoietin (EPO)
10995569	10995569	Atellica IM Ferritin (Fer)
10995568	10995568	Atellica IM Ferritin (Fer)
10995572	10995572	Atellica IM Folate (Fol)
10995573	10995573	Atellica IM Folate (Fol)
10995714	10995714	Atellica IM Vitamin B12 (VB12)
10995715	10995715	Atellica IM Vitamin B12 (VB12)
10732998	10732998	Atellica IM anti-CCP IgG (aCCP)
10995621	10995621	Atellica IM Intact Parathyroid Hormone (PTH)
10995622	10995622	Atellica IM Intact Parathyroid Hormone (PTH)
10995719	10995719	Atellica IM Vitamin D Total (VitD)
10995720	10995720	Atellica IM Vitamin D Total (VitD)
10995541	10995541	Atellica IM C-peptide (CpS)
10995628	10995628	Atellica IM Insulin (IRI)
10733011	10733011	Atellica IM IL-6 Interleukin 6 (IL6)
10733015	10733015	Atellica IM Lipopolysaccharide Binding Protein (LBP)
10995695	10995695	Atellica IM Tissue Inhibitor of Matrix Metalloproteinase 1 (TIMP-1)
10995595	10995595	Atellica IM Hyaluronic Acid (HA)
10995653	10995653	Atellica IM N-terminal Propeptide of Type III Procollagen (PIIINP)
10995538	10995538	Atellica IM Cortisol (Cor)
10995537	10995537	Atellica IM Cortisol (Cor)
10995606	10995606	Atellica IM Homocysteine (HCY)
10995607	10995607	Atellica IM Homocysteine (HCY)
11200558	11200558	Atellica IM Androstenedione
10995555	10995555	Atellica IM DHEA-SO4 (DHEAS)
10995561	10995561	Atellica IM Enhanced Estradiol (eE2)

Siemens Material Number	Part Number	Product Description
10995562	10995562	Atellica IM Enhanced Estradiol (eE2)
10995580	10995580	Atellica IM Follicle Stimulating Hormone (FSH)
10995581	10995581	Atellica IM Follicle Stimulating Hormone (FSH)
10995635	10995635	Atellica IM Luteinizing Hormone (LH)
10995634	10995634	Atellica IM Luteinizing Hormone (LH)
10995660	10995660	Atellica IM Progesterone (PRGE)
10995659	10995659	Atellica IM Progesterone (PRGE)
10995656	10995656	Atellica IM Prolactin (PRL)
10995655	10995655	Atellica IM Prolactin (PRL)
10995672	10995672	Atellica IM Sex Hormone Binding Globulin (SHBG)
10995708	10995708	Atellica IM Testosterone II (TSTII)
10995707	10995707	Atellica IM Testosterone II (TSTII)
10995690	10995690	Atellica IM Total hCG (ThCG)
10995689	10995689	Atellica IM Total hCG (ThCG)
10995461	10995461	Atellica IM Anti-Thyroglobulin (aTG)
10995462	10995462	Atellica IM Anti-Thyroglobulin (aTG)
11201759	11201759	Atellica IM Anti-Thyroglobulin II (aTgII)
11201761	11201761	Atellica IM Anti-Thyroglobulin II (aTgII)
10995466	10995466	Atellica IM Anti-Thyroid Peroxidase (aTPO)
10995467	10995467	Atellica IM Anti-Thyroid Peroxidase (aTPO)
10995585	10995585	Atellica IM Free Triiodothyronine (FT3)
10995584	10995584	Atellica IM Free Triiodothyronine (FT3)
10995589	10995589	Atellica IM Free Thyroxine (FT4)
10995588	10995588	Atellica IM Free Thyroxine (FT4)
11200450	11200450	Atellica IM Thyroglobulin II (Tg)
11200534	11200534	Atellica IM Thyroglobulin II (Tg)
10995679	10995679	Atellica IM Total Triiodothyronine (T3)
10995678	10995678	Atellica IM Total Triiodothyronine (T3)
10995684	10995684	Atellica IM Total Thyroxine (T4)
10995685	10995685	Atellica IM Total Thyroxine (T4)
10995703	10995703	Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)
10995704	10995704	Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)

Siemens Material Number	Part Number	Product Description
10995712	10995712	Atellica IM Thyroid Uptake (TUp)
10995711	10995711	Atellica IM Thyroid Uptake (TUp)
11208300	11208300	ADVIA Centaur sCOVG Diluent (2PK)
10309985	06843687	ADVIA Centaur Total IgE (tIgE)
10309986	03359776	ADVIA Centaur Total IgE (tIgE)
10309968	07875728	ADVIA Centaur Ferritin (FER)
10309969	00495776	ADVIA Centaur Ferritin (FER)
10310308	06367974	ADVIA Centaur Folate (FOL)
10325366	06891541	ADVIA Centaur Folate (FOL)
10309970	07847260	ADVIA Centaur VB12
10330218	09544818	ADVIA Centaur VB12
10995088	10995088	ADVIA Centaur Active-B12 (AB12)
10995096	10995096	ADVIA Centaur Erythropoietin (EPO)
10699201	10699201	ADVIA Centaur Vitamin D Total (VitD)
10699533	10699533	ADVIA Centaur Vitamin D Total (VitD)
10699154	10699154	ADVIA Centaur PTH
10699155	10699155	ADVIA Centaur PTH
10310448	03649928	ADVIA Centaur C-peptide (CpS)
10994924	10994924	ADVIA Centaur Cortisol (COR)
10994926	10994926	ADVIA Centaur Cortisol (COR)
10310374	05370300	ADVIA Centaur HCY
10310375	09087913	ADVIA Centaur HCY
10309973	04912924	ADVIA Centaur FSH
10309974	01360521	ADVIA Centaur FSH
10309971	01756298	ADVIA Centaur LH
10309972	02212941	ADVIA Centaur LH
10490889	10490889	ADVIA Centaur Enhanced Estradiol (eE2)
10491445	10491445	ADVIA Centaur Enhanced Estradiol (eE2)
10310305	02382928	ADVIA Centaur Progesterone (PRGE)
10315522	01586287	ADVIA Centaur Progesterone (PRGE)
10309975	03278474	ADVIA Centaur Prolactin (PRL)
10309976	09505871	ADVIA Centaur Prolactin (PRL)

Siemens Material Number	Part Number	Product Description
10308984	00638631	ADVIA Centaur Total hCG (ThCG)
10308985	00643953	ADVIA Centaur Total hCG (ThCG)
10696862	10696862	ADVIA Centaur Testosterone II (TSTII)
10696863	10696863	ADVIA Centaur Testosterone II (TSTII)
10997191	10997191	ADVIA Centaur SHBG
10995084	10995084	ADVIA Centaur LBP
10995080	10995080	ADVIA Centaur IL6
11201758	11201758	ADVIA Centaur Anti-Thyroglobulin II (aTgII)
11201760	11201760	ADVIA Centaur Anti-Thyroglobulin II (aTgII)
10630886	10630886	ADVIA Centaur anti-TPO (aTPO)
10630887	10630887	ADVIA Centaur anti-TPO (aTPO)
10310317	01131417	ADVIA Centaur FT3
10310318	03154228	ADVIA Centaur FT3
10282218	06490092	ADVIA Centaur FT4
10282219	06490106	ADVIA Centaur FT4
10285733	04779671	ADVIA Centaur T3
10285732	04779663	ADVIA Centaur T3
10309960	08074354	ADVIA Centaur T4
10309961	09236439	ADVIA Centaur T4
10282378	06491072	ADVIA Centaur TSH3-Ultra
10282379	06491080	ADVIA Centaur TSH3-Ultra