



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
- 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 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)
- 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
11417929	11417929	Atellica IM Acid
11417930	11417930	Atellica IM Base
11098501	11098501	Atellica IM Wash
11098502	11098502	Atellica IM Cleaner
10995666	10995666	Atellica IM Probe Wash 3 (PW3)
10995458	10995458	Atellica IM Ancillary Probe Wash 1 (APW1)
10998580	10998580	Atellica IM Ancillary Probe Wash 3 (APW3)
10995637	10995637	Atellica IM Multi-Diluent 1
10995638	10995638	Atellica IM Multi-Diluent 1
10995639	10995639	Atellica IM Multi-Diluent 1
10995644	10995644	Atellica IM Multi-Diluent 2
10995645	10995645	Atellica IM Multi-Diluent 3
10995647	10995647	Atellica IM Multi-Diluent 5
10995640	10995640	Atellica IM Multi-Diluent 10
10995642	10995642	Atellica IM Multi-Diluent 11
10995641	10995641	Atellica IM Multi-Diluent 11
10995550	10995550	Atellica IM Multi-Diluent 12
10995643	10995643	Atellica IM Multi-Diluent 13
11200662	11200662	Atellica IM Multi-Diluent 14
11200798	11200798	Atellica IM Multi-Diluent 15
10995682	10995682	Atellica IM T3/T4/VB12 Ancillary Reagent (T3/T4/VB12 ANC)
10995683	10995683	Atellica IM T3/T4/VB12 Ancillary Reagent (T3/T4/VB12 ANC)
10319550	03773025	ADVIA Centaur Wash 1 Reagent for Centaur XP only
10310032	01137199	ADVIA Centaur Wash 1 Reagent for Centaur/Centaur CP
10310026	03852677	ADVIA Centaur Acid/Base reagent for Centaur/Centaur XP
10313526	00497043	ADVIA Centaur Acid/Base reagent for Centaur CP only
10334314	03333963	ADVIA Centaur Probe Wash 3
10321290	04750940	ADVIA Centaur Probe Wash 4
10309060	03395373	ADVIA Centaur Ancillary Probe Wash 1
10316997	02416113	ADVIA Centaur CP Ancillary Probe Wash 2

Siemens Material Number	Part Number	Product Description
10699211	10699211	ADVIA Centaur Ancillary Probe Wash 3
10310041	09908593	ADVIA Centaur Cleaning Solution Concentrate
10309941	07907174	ADVIA Centaur Multi-Diluent 1 (2PK)
10309942	07293184	ADVIA Centaur Multi-Diluent 1 (6PK)
10309943	07948423	ADVIA Centaur Multi-Diluent 2 (2PK)
10309944	05389133	ADVIA Centaur Multi-Diluent 3 (2PK)
10310280	05440554	ADVIA Centaur Multi-Diluent 10 (2PK)
10310281	05699280	ADVIA Centaur Multi-Diluent 11 (2PK)
10998501	10998501	ADVIA Centaur Multi-Diluent 14 (6PK)
10311571	09348792	ADVIA Centaur Multi-Diluent 1
10335692	04786546	ADVIA Centaur Multi-Diluent 12
10319315	03644012	ADVIA Centaur T3/T4/VB12 Ancillary Reagent (2PK)
10309954	01514596	ADVIA Centaur T3/T4/VB12 Ancillary Reagent (6PK)