Siemens Healthcare Diagnostics Inc.
511 Benedict Ave., Tarrytown, NY 10591, USA

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Date March 30, 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 below medical devices comply to the standards mentioned in Attachment 1.

Bhandari Komal

Digitally signed by Bhandari Komal
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Date: 2022.03.30 17:02:08 +05'30'

Komal Bhandari
Regulatory Affairs Professional

Attachment 1:

Siemens Material Number	Part number	Article Number	Product Description	EN ISO 13485:2016	EN 13612:2002 EN 13612:2002/AC:2002	EN 13640:2002	EN 13641:2002	EN ISO 14971:2012	EN ISO 15223-1:2016	EN ISO 17511:2003	EN ISO 18113-1:2011	EN ISO 18113-2: 2011	EN ISO 18513: 2013	EN ISO 23640:2015	EN 62366:2008	EN 980:2008
10341169	T01-3626-52	08008297	ADVIA 120/2120/2120i CN-Free CBC TIMEPAC	x	x	-	x	x	x	-	x	x	-	x	x	-
10312269	T01-3620-52	09826813	ADVIA 120/2120/2120i CBC TIMEPAC	x	x	-	x	x	x	-	x	x	-	x	x	-
10312270	T01-3621-52	00739500	ADVIA 120/2120/2120i DIFF TIMEPAC	x	x	-	x	x	x	-	x	x	-	x	x	-
10312271	T01-3622-54	04296794	ADVIA 120/2120/2120i autoRETIC	x	x	-	x	x	x	-	x	x	-	x	x	-
10330709	T01-3622-51	09812782	ADVIA 120/2120/2120i autoRETIC	x	x	-	x	x	x	-	x	x	-	x	x	-
10312275	T01-3633-54	03624240	ADVIA 120/2120/2120i PEROX SHEATH	x	x	-	x	x	x	-	x	x	-	x	x	-
10312274	T01-3625-54	09119084	ADVIA 120/2120/2120i DEFOAMER	x	x	-	x	x	x	-	x	x	-	x	x	-
10320459	T01-4610-01	04274197	ADVIA 120/2120/2120i CSF Reagent	x	x	x	x	x	x	-	x	x	-	x	x	x
10312272	T01-3623-01	01554628	ADVIA 120/2120/2120i Sheath/Rinse (20L)	x	x	-	x	x	x	-	x	x	-	x	x	-
10285021	4871500	04871500	ADVIA 120/2120/2120i EZ WASH	x	x	-	x	x	x	-	x	x	-	x	x	-
10312283	T03-3682-54	08100525	ADVIA 120/2120/2120i OPTIpoint	x	x	-	x	x	x	x	x	x	-	x	x	-
10312285	T03-3685-52	09170071	ADVIA 120/2120/2120i SETPoint Calibrator	x	x	x	x	x	x	x	x	x	-	x	x	x
10330063	T03-4417-54	09459683	ADVIA 120/2120/2120i 3·in·1 TESTpoint Heamatology Controls (Abnormal Control 1)	x	x	x	x	x	x	x	x	x	-	x	x	x

10316217	T03-4416-54	01964346	ADVIA 120/2120/2120i 3-in-1 TESTpoint Heamatology Controls (Normal Control)	x	x	x	x	x	x	x	x	x	-	x	x	x
10318905	T03-4418-54	03410380	ADVIA 120/2120/2120i 3-in-1 TESTpoint Heamatology Controls (Abnormal Control 2)	x	x	x	x	x	x	x	x	x	-	x	x	x
10312287	T03-3686-54	00848547	ADVIA 120/2120/2120i TESTpoint Heamatology Controls (Low Control)	x	x	x	x	x	x	x	x	x	-	x	x	x
10312289	T03-3687-54	05147873	ADVIA 120/2120/2120i TESTpoint Heamatology Controls (Normal Control)	x	x	x	x	x	x	x	x	x	-	x	x	x
10312291	T03-3688-54	08822644	ADVIA 120/2120/2120i TESTpoint Heamatology Controls (High Control)	x	x	x	x	x	x	x	x	x	-	x	x	x
10314243	T03-4485-01	00872863	ADVIA 120/2120/2120i CSF Controls	x	x	x	x	x	x	x	x	x	-	x	x	x
11170845	D1512	11170845	ADVIA 360/560 Diluent	x	x	x	-	x	x	-	x	x	-	x	x	x
11170848	D2011HK	11170848	ADVIA 360 Lyse 3P Diff	x	x	x	-	x	x	-	x	x	-	x	x	x
11170849	D5011	11170849	ADVIA 360 Cleaner	x	x	x	-	x	x	-	x	x	-	x	x	x
11170846	D3015	11170846	ADVIA 560 Lyse	x	x	x	-	x	x	-	x	x	-	x	x	x
11170847	D3021	11170847	ADVIA 560 5P Diff	x	x	x	-	x	x	-	x	x	-	x	x	x
11170850	D7011	11170850	ADVIA 360/560 Hypoclean	x	x	x	-	x	x	-	x	x	-	x	x	x
11170851	D8011	11170851	ADVIA 360/560 Hypoclean CC	x	x	x	-	x	x	-	x	x	-	x	x	x
11170852	8CD02	11170852	ADVIA 360/560 Calibrator	x	x	x	x	x	x	x	x	x	-	x	x	x
11170853	D3D02	11170853	ADVIA 360 Control	x	x	x	x	x	x	x	x	x	-	x	x	x
11170854	D3D02	11170854	ADVIA 560 Control	x	x	x	x	x	x	x	x	x	-	x	x	x
10718483	-	10718483	ADVIA Autoslide Giemsa Stain	x	x	x	x	x	x	-	x	x	-	x	x	x
10718482	-	10718482	ADVIA Autoslide May-Grunwald Stain	x	x	x	x	x	x	-	x	x	-	x	x	x
10718484	-	10718484	ADVIA Autoslide May-Grunwald Giemsa Buffer	x	x	x	x	x	x	-	x	x	-	x	x	x
10327568	08096536	08096536	ADVIA Autoslide Wright-Giemsa Stain	x	x	x	x	x	x	-	x	x	-	x	x	x

10327572	08097532	08097532	ADVIA Autoslide Wright Giemsa Buffer	x	x	x	x	x	x	-	x	x	-	x	x	x
10327576	08100142	08100142	ADVIA Autoslide Modified Wright's Stain	x	x	x	x	x	x	-	x	x	-	x	x	x
10327577	08100290	08100290	ADVIA Autoslide Modified Wright Buffer	x	x	x	x	x	x	-	x	x	-	x	x	x
10325262	06837687	06837688	ADVIA Autoslide Rinse	x	x	x	x	x	x	-	x	x	-	x	x	x
11374308	-	-	Atellica HEMA Baso	x	x	-	-	x	x	-	x	x	-	x	x	x
11374309	-	-	Atellica HEMA RET PLTO	x	x	-	-	x	x	-	x	x	-	x	x	x
11374310	-	-	Atellica HEMA Diff	x	x	-	-	x	x	-	x	x	-	x	x	x
11374312	-	-	Atellica HEMA Calibrator	x	x	-	-	x	x	x	x	x	-	x	x	-
11374316	-	-	Atellica HEMA Control RETIC	x	x	-	x	x	x	x	x	x	-	x	x	-
11374317	-	-	Atellica HEMA Control RETIC	x	x	-	x	x	x	x	x	x	-	x	x	-
11374318	-	-	Atellica HEMA Control RETIC	x	x	-	x	x	x	x	x	x	-	x	x	-
11374319	-	-	Atellica HEMA Control BF	x	x	-	x	x	x	x	x	x	-	x	x	-
11374320	-	-	Atellica HEMA Control BF	x	x	-	x	x	x	x	x	x	-	x	x	-
11374303	-	-	Atellica HEMA Diluent	x	x	-	-	x	x	-	x	x	-	x	x	-
11374304	-	-	Atellica HEMA Diluent	x	x	-	-	x	x	-	x	x	-	x	x	-
11374306	-	-	Atellica HEMA Cleaner	x	x	-	-	x	x	-	x	x	-	x	x	-
11374311	-	-	Atellica HEMA Decon	x	x	-	-	x	x	-	x	x	-	x	x	-
10734561	10734561	10734561	ADVIA 2120 and ADVIA 2120i RBC Flow Cell Wash	x	x	-	x	x	x	x	x	x	x	x	x	-
11306489	11306489	11306489	ADVIA 2120 and ADVIA 2120i Perox Flow Cell Wash	x	x	-	x	x	x	x	x	x	x	x	x	-
11306490	11306490	11306490	ADVIA 2120 and ADVIA 2120i Aspiration Pathway Wash	x	x	-	x	x	x	x	x	x	x	x	x	-
11306492	11306492	11306492	ADVIA 2120 and ADVIA 2120i Vent Line Wash	x	x	-	x	x	x	x	x	x	x	x	x	-

Standard title:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN 13612:2002 EN13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13640:2002	Stability testing of in vitro diagnostic reagents
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 14136:2004	Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures
EN ISO 14971:2012	Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
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)
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 18113-3: 2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)
EN ISO 18153:2003	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))
EN ISO 23640:2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
IEC 60601-1-2 :2014	Medical electric equipment Part 1-2: general requirements for basic safety and essential performance
EN 60825-1: 2014	Safety of laser products – Part 1: Equipment classification and requirements (IEC 60825-1:2014)
EN 61010-1: 2010	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (IEC 61010-1:2010)
IEC 61010-2-081: 2019	Safety requirements for electrical equipment for measurement, control and laboratory us. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.

EN 61010-2-101: 2002 / 2015 / 2017	Safety requirements for electrical equipment for measurement, control, and laboratory use —Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61010-2-101:2002 (Modified)
EN 61326-1: 2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements (IEC 61326-1:2012)
EN 61326-2-6: 2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2012)
EN 62304: 2006/AC:2008	Medical device software — Software life-cycle processes (IEC 62304:2006)
EN 62366:2008	Medical devices — Application of usability engineering to medical devices IEC 62366:2007
EN IEC 63000: 2018	Technical documentation for the assessment of electrical and electronic products with respect to restriction of hazardous substances.
EN 980:2008	Graphical symbols for use in the labelling of medical devices