Siemens Healthcare Diagnostics Inc.
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Date November XX, 20XX

To whom it may concern,

We, **Siemens Healthcare Diagnostics Inc.**, located at 62 Flanders-Bartley Road, Flanders, NJ 07836, 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	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 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 18113-3:2011	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 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)
EN 61010-2-101:2002	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 IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
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/A1:2014)
IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices

Nithesh Rangaswamy Balaraman
Regulatory Affairs Professional

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Attachment 1

Siemens Material Number	Part Number	Product Description
10385183	LSCC	IMMULITE / IMMULITE 1000 Systems 1000 Sample Cup Caps (Disposable)
10380037	LSCP	IMMULITE / IMMULITE 1000 Systems Sample Cups
10385206	LRXT	IMMULITE 2000 Systems Reaction Tubes
10282837	L2ATC	IMMULITE 2000 Systems Allergen Tube Caps
10282849	L2ATS2	IMMULITE 2000 Allergen Tube Septa
10385207	LMST	IMMULITE 2000 Systems Microsampling Tubes
10374178	905288	IMMULITE 2000 Nesting Cups 1 mL for 12-mm and 13-mm sample tubes
10374179	905289	IMMULITE 2000 Nesting Cups 2 mL