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 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 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)

For and on behalf of
Siemens Healthcare Diagnostics Inc.

Camposano Elena

Digitally signed by Camposano Elena
DN: serialNumber=Z003M6WC, givenName=Elena, sn=Camposano, o=Siemens, cn=Camposano Elena
Reason: I am approving this document
Date: 2022.03.23 11:49:37 -04'00'

Elena Camposano
Regulatory Affairs Specialist

Siemens Healthcare Diagnostics Inc.
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Attachment 1

Siemens Material Number	Part Number	Product Description
11069061	11069061	Atellica Tube Top Sample Cup (1 ml)
11069062	11069062	Atellica Tube Top Sample Cup (2 ml)