April 6, 2022

To Whom It May Concern:

Please find the Summary of Referenced Standards in the table below for the following products: ADVIA Centaur® Cuvettes, Sample Cups and Sample Tips (SMNs 10309546, 10309545, 10309547).

## Appendix 1 – Summary of Referenced Standards

| Standard Number and Title (International Standard) | Applicable Essential Requirement(s) | Name, Address and Accreditations of Third-Party Certification Organization | Comments |
|---|---|---|---|
| **EN ISO 13485:2016/AC:2016**<br>*Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)* | Applies to overall Quality Management System | Lloyd's Register Quality Assurance, Inc.<br>1401 Enclave Parkway, Suite 200<br>Houston, TX, USA, 77077<br><br>*Relevant Accreditations:*<br>ISO/IEC 17021:2011<br>CAN-P-16:2011<br>CAN-P-1517:2013 | The Quality Management System of Siemens Healthcare Diagnostics Inc. (Tarrytown, NY and associated sites) was certified to ISO 13485:2016. Compliance to EN ISO 13485:2016/AC:2016 is established by conformity assessment to the requirements of the European IVD Directive (98/79/EC). See QP-ER-TTN-02: EN ISO 13485:2016 Quality Plan. |
| **EN 13612:2002/AC:2002**<br>*Performance evaluation of in vitro diagnostic medical devices* | A.3, B.4.1, B.6.1 | N/A | N/A |
| **EN ISO 14971:2012**<br>*Medical devices – Application of risk management to medical devices (ISO 14971:2007)* | A.1, A.2 | N/A | N/A |
| **EN ISO 15223-1:2016**<br>*Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016)* | B.8.1, B.8.2, B.8.4(a), B.8.4(b), B.8.4(d), B.8.4(g), B.8.4(h), B.8.4(i), B.8.4(j), B.8.6 | N/A | N/A |

| | | | |
|---|---|---|---|
| **EN ISO 18113-1:2011**<br>*In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)* | B.8.1, B.8.2, B.8.4(j) | N/A | N/A |

| **Standard Number and Title (International Standard)** | **Applicable Essential Requirement(s)** | **Name, Address and Accreditations of Third-Party Certification Organization** | **Comments** |
|---|---|---|---|
| **EN 62366:2008**<br>*Medical devices -- Application of usability engineering to medical devices (IEC 62366:2007/A1:2014)* | A.1, A.2 | N/A | Assessed according to IEC 62366-1:2015 (Medical devices -- Part 1: Application of usability engineering to medical devices).<br>This standard is an administrative update to IEC 62366:2007/A1:2014. |

On Behalf of Siemens Healthcare Diagnostics:

Annmarie Harris
Regulatory Affairs Professional

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
Tel.: +1 914-631-8000
usa.siemens.com/healthineers