

## STANDARD INFORMATION

### Standards:

**UL 61010-2-081:2015 Ed.2 / CSA C22.2 No. 61010-2-081:2015 Ed.2 / IEC 61010-2-081:2015 Ed.2**

**UL 61010-2-081:2020 Ed.3 / CSA C22.2 No. 61010-2-081:2020 Ed.3 / IEC 61010-2-081:2019 Ed.3**

Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-081: Particular Requirements for Automatic and Semi-Automatic Laboratory Equipment for Analysis and Other Purposes

**UL 61010-2-101:2015 Ed.2 / CSA C22.2 No. 61010-2-101:2015 Ed.2 / IEC 61010-2-101:2015 Ed.2**

**UL 61010-2-101:2019 Ed.3 / CSA C22.2 No. 61010-2-101:2019 Ed.3 / IEC 61010-2-101:2018 Ed.3**

Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment

## EFFECTIVE DATE OF NEW/REVISED REQUIREMENTS

**Effective Date:** **April 12, 2021**

## IMPACT, OVERVIEW, AND ACTION REQUIRED

**Impact Statement:** The scope of UL/CSA/IEC 61010-2-081 excludes IVD medical equipment, vs UL/CSA/IEC 61010-2-101 excludes equipment within the scope of IEC 61010-2-081 which is not intended for IVD examination. This means that IVD medical equipment cannot be listed to both particular standards; one listing report cannot include both IVD and non-IVD models, as different particular standards apply to such models.

- For product listings which cover IVD models only, but where currently both particular standards are referenced, UL/CSA/IEC 61010-2-081 must be removed prior to the effective date.
- For product listings which cover both IVD and non-IVD models, and where both particular standards are referenced, the non-IVD models have to be identified and transferred to a separate listing report prior to the effective date.

### Client Action Required:

To assist Intertek with the no-charge revision of the existing listing report to state the correct standards and, where applicable, to transfer non-IVD models to a separate listing report, the client must respond in writing within 180 days or the listing(s) will be withdrawn on the Effective Date noted above:

- Confirming that the listing report includes IVD medical equipment models only, which conform to CSA/UL/IEC 61010-2-101, and



- Identifying the non-IVD equipment conforming with CSA/UL/IEC 61010-2-081, which will have to be transferred to a separate listing report.

***Current Listings Not Active? – Please immediately identify any current Listing Reports or products that are no longer active and should be removed from our records. We will do this at no charge as long as Intertek is notified in writing prior to the review of your reports.***