STANDARDS UPDATE NOTICE (SUN)
ISSUED: November 28, 2018

STANDARD INFORMATION

This SUN establishes the Continuing Certification approach for In Vitro Diagnostic (IVD) medical equipment

Standard Number: CSA C22.2 No. 61010-2-101
Standard Name: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use — Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
Standard Edition and Issue Date: 2nd Edition Dated October 1, 2015
Date of Revision: October 1, 2015
Date of Previous Revision of Standard: 1st Edition Reaffirmed 2014

EFFECTIVE DATE OF NEW/REVISED REQUIREMENTS

Effective Date: **No action is required for currently certified products to maintain certification.**

This SUN is being presented to assist users of the standard to appreciate the significance of the changes made to the standard that will apply should the product described be modified after January 1, 2019.

IMPACT, OVERVIEW, AND ACTION REQUIRED

Impact Statement: A review of all Listing Reports is necessary to determine which products comply with new/revised requirements and which products will require re-evaluation. **NOTE:** Effective immediately, this revised standard will be exclusively used for evaluation of new products unless the Applicant requests in writing that current requirements be used along with their understanding that their listings will be withdrawn on Effective Date noted above, unless the product is found to comply with new/revised requirements.

Overview of Changes:

- Updated Biohazard and Lot symbols in Table 1
- Added requirement for within expiration consumables and authorized representative details
- Added requirement for gas or liquid markings and ratings
- Added normative reference ISO 18113-5 for instructions for use of self-test IVD medical equipment
- Added requirement for OPERATOR maintenance instructions
- Added requirement for biohazard marking

Specific details of new/revised requirements are found in table below.

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 – Please immediately identify any current Listing Reports or products that are no longer active and should be removed from our records.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.

STANDARD INFORMATION

CLAUSE	VERDICT	COMMENT
		Additions to existing requirements are underlined and deletions are shown lined out below.
5	Info	**Marking and documentation**
Table 1		Additions: Add the following symbol to Table 1: **Symbols** **Number** / **Symbol** / **Publication** / **Description** ~~101~~ /  ~~Background colour – yellow Symbol and outline – black~~ / ~~ISO 7000 – 0659~~ / ~~Biohazard~~ 101 /  Background colour – optional; Symbol colour – optional; Outline / outline colour – optional; / ISO 7000-0659 (2004-01) / Biological risks 102 /  / ~~EN 980, subclause 4~~ ISO 7000- 2492 (2004-01) / Batch code
5.1.2		**Identification** Replacement: Replace the text by the following: Equipment shall, as a minimum, be marked with the following information: a) manufacturer's name or trade mark, and the address. The address shall include at least the city and country; NOTE 1 National regulation may require more details on the address than required in a). b) model number, name, or other means of identifying the equipment; The following additional information shall be marked on the equipment or packaging or in the instructions for use: 1) the serial number, for example SN XXXX or alternatively the batch code, preceded by 'LOT', using symbol 102 of Table 1;

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		2) the following information: i) a clear indication that the equipment is IVD medical equipment; ii) if applicable, a clear indication that the equipment is self-test IVD medical equipment; iii) if a potential RISK is posed, the identification of detachable components by manufacturer and part identification, and where appropriate the batch code, etc. ~~iv) any expiry date of consumable parts, expressed as the year, the month and (where relevant) the day, in that order.~~ 3) instructions for use shall require that the OPERATOR only use consumables that are within their expiration date. Where this is required by regulation, the name and address of the authorized representative of the manufacturer. NOTE 2 For example, in the European Union this is the natural or legal person as established within the European Community.
5.1.5.101		***New clause added;*** **Gas and liquid connections** If necessary for safety, the equipment shall be clearly marked near to the connector on the equipment with; a) a means of identifying the gas or liquid to be used. Where no internationally recognized symbol (including chemical formulae) exists, the equipment shall be marked with symbol 14 of Table 1; b) the maximum permitted pressure, or alternatively symbol 14 of Table 1 (see 5.4.3). Conformity is checked by inspection.
5.4.4		**Equipment operation** Replacement: Replace the first paragraph text by the following: Instructions for use shall include if applicable: m) detailed instructions about RISK reduction procedures relating to flammable liquids (see 9.5 c)); n) details of methods of reducing the RISKS of burns from surfaces permitted to exceed the temperature limits of 10.1. o) Appropriate warnings to reduce RISK during loading and unloading of samples and reagents (see 7.3.102) p) Instructions for the RESPONSIBLE BODY to ensure that all retaining hardware (e.g

CLAUSE	VERDICT	COMMENT
		screws, fasteners) are in place on removable PROTECTIVE BARRIERS, and the removable PROTECTIVE BARRIERS are in place on the instrument during normal operation. q) A statement that, if a TOOL is required to remove a fixed PROTECTIVE BARRIER and/or ENCLOSURE guarding a SAMPLE ZONE, access to that tool should be controlled by the RESPONSIBLE BODY. r) A statement listing the tools to be controlled by the RESPONSIBLE BODY.
5.4.4.101		**Instructions for use, self-test IVD medical equipment** Instructions for use of self-test IVD medical equipment ~~are given in annex BB~~ shall comply with ISO 18113-5.
7	Info	**Protection against mechanical HAZARDS**
7.3.1		***New clause added;*** **General** Replacement: Replace the second sentence as follows: The conditions specified in 7.3.4, 7.3.5, and 7.3.101 are considered to represent a tolerable level. Replace the conformity statement as follows: Conformity is checked as specified in 7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.101, and Clause 17 as applicable.
7.3.2		***New clause added;*** **Exceptions** Replacement: Replace item b) 3) text by the following: There are warning markings prohibiting access by untrained OPERATORS. Markings shall be placed within the area requiring maintenance where they can alert the OPERATOR to the HAZARD. As an alternative, symbol 14 of Table 1 can be used, with the warnings included in the documentation. Addition: Add the following item to the list: b) 4) There are OPERATOR maintenance instructions that specify safe maintenance procedures.

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		New clause added; **RISK assessment for mechanical HAZARDS to body parts** Replacement: Replace text by the following: If equipment is specified by the manufacturer for continuous loading of sample and reagent materials and associated HAZARDS in the SAMPLE ZONE are solely caused by the sample and/or reagent probes 7.3.101 applies specifically for the SAMPLE ZONE. Subclause 7.3.101 does not apply to self-testing and point of care equipment.
7.3.3		RISKS shall be reduced to a tolerable level by at least the applicable minimum protective measure of Table 12, taking into account the severity, probability of exposure and possibility of avoiding the HAZARD. Conformity is checked by evaluation of the RISK assessment documentation to ensure that the RISKS have been eliminated or that only TOLERABLE RISKS remain. Table 12 – Protective measures against mechanical HAZARDS to body parts Replacement: Replace the text of item B by the following text: Moderate measures; emergency switches, PROTECTIVE BARRIERS or covers removable only with a TOOL, distances (see ISO 13857), or separations (see ISO 13854 or EN 349).
7.3.101		**SAMPLE ZONE** Equipment with a SAMPLE ZONE shall comply with the requirements of one or more of the following: aa) PROTECTIVE BARRIER or bb) all following measures apply: 1) The minimum maintained gap between LOADING ZONE and SAMPLE ZONE is 120 mm. 2) Unintentional contact between OPERATOR and sample/reagent pipettor is unlikely. 3) The area between LOADING ZONE and SAMPLE ZONE is marked with symbol 14 and symbol 101 of table 1 (see 5.4.4 o)), or if not visible by the OPERATOR the marking shall be located visible and close to the area.

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8	Info	**Resistance to mechanical stresses**
8.1		***New clause added;*** **General** Replacement: Replace the text of item 3) by the following: 3) except for FIXED EQUIPMENT, for equipment with a mass over 100 kg, or for equipment whose size and weight make unintentional movement unlikely and which is not moved in NORMAL USE, the appropriate test of 8.3. The equipment is not operated during the tests.
13	Info	**Protection against liberated gases and substances, explosion and implosion**
13.101		**Biohazardous substances** Equipment that can be potentially infectious due to the samples or reagents used shall be prominently marked with symbol 101 of Table 1. At minimum, a biohazard symbol shall be near the sampling area and visible in NORMAL USE. Biohazard symbols shall be near biohazardous areas accessed during OPERATOR maintenance visible only during this maintenance. Symbol 101 of Table 1 shall be marked on containers or bags for biohazardous waste material which can be removed from the equipment during NORMAL USE, and near any biohazardous drain connection. Equipment that can be hazardous due to the use of hazardous substances shall be marked with the appropriate international symbol, or (if none is available) symbol 14 of Table 1.
17		***New clause added;*** **RISK assessment** This clause of Part 1 is replaced as follows: Replacement: RISK assessment shall be carried out and documented using the requirements of ISO 14971 for HAZARDS not addressed in this standard and Part 1. Conformity is checked by evaluation of the RISK assessment documentation to assure that the RISKS have been eliminated or that only TOLERABLE RISKS remain.
		CUSTOMERS PLEASE NOTE: This Table and column “Verdict” can be used in determining how your current or future production is or will be in compliance with new/revised requirements.