



## New Standards & Editions

**CAN/CSA-ISO 10993-1-01, 2nd edition**  
*Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing* (Adopted ISO 10993-1:1997, second edition) . . . . . \$50

This standard describes the following:

- a) the general principles governing the biological evaluation of medical devices
- b) the categorization of devices based on the nature and duration of their contact with the body
- c) the selection of appropriate tests.

**CAN/CSA-ISO 10993-5-01, 2nd edition**  
*Biological Evaluation of Medical Devices—Part 5: Tests for In Vitro Cytotoxicity* (Adopted ISO 10993-5:1999, second edition) . . . . . \$40

This standard describes test methods for assessing the in vitro cytotoxicity of medical devices. These methods specify the incubation of cultured cells (either directly or through diffusion) with extracts of a device and/or in contact with a device. The methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.

**CAN/CSA-M3776-00, 1st edition**  
*Tractors for Agriculture—Seat Belt Anchorages* (Adopted ISO 3776:1989, second edition) . . . . . \$30

This standard specifies requirements for: the location of the anchorages for pelvic restraint belts for operators of agricultural tractors fitted with a cab or frame; the force that the anchorages must be able to withstand; and the tests the anchorages must be subjected to.

**CAN/CSA-Z8835-2-01, 1st edition**  
*Inhalational Anaesthesia Systems—Part 2: Anaesthetic Breathing Systems for Adults* (Adopted ISO 8835-2:1999, second edition) . . . . . \$80

This standard specifies requirements for inhalational anaesthetic breathing systems for adults, which are supplied either assembled by the manufacturer or for assembly by the user. It also covers circle absorber assemblies, exhaust valves, and inspiratory and expiratory valves. In some designs, it also covers the parts of an anaesthetic breathing system that are incorporated in an anaesthetic workstation, including the expiratory gas pathway of an anaesthetic ventilator and any parts of a non-operator-detachable anaesthetic-gas scavenging system (AGSS).

**CAN/CSA-Z8836-01, 2nd edition**  
*Suction Catheters for Use in the Respiratory Tract* (Adopted ISO 8836:1997, second edition) . . . . . \$65

This standard specifies requirements for plastic suction catheters for use in suction of the respiratory tract.

It does not cover specialized suction catheters (such as those with more than one lumen). It does cover angled-tip suction catheters (such as Coudé catheters), which are not considered specialized.

The following six standards were developed by the International Electrotechnical Commission (IEC), and have been adopted by CSA International.

**CAN/CSA-C22.2 No. 601.2.3A-01**  
*Amendment 1:2001 to CAN/CSA-C22.2 No. 601.2.3-92, “Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Short-Wave Therapy Equipment”* (Adopted Amendment 1:1998 to IEC 601-2-3 (1991), without modification) . . . . . \$130

**CAN/CSA-C22.2 No. 601.2.17A-01 (bilingual)**  
*Amendment 1:2001 to CAN/CSA-C22.2 No. 601.2.17-94, “Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Remote-Controlled Automatically-Driven Gamma-Ray Afterloading Equipment”* (Adopted Amendment 1:1996 to IEC 601-2-17 (1989), without modification) . . . . . \$85

**CAN/CSA-C22.2 No. 601.2.19A-01 (bilingual)**  
*Amendment 1:2001 to CAN/CSA-C22.2 No. 601.2.19-92, “Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Baby Incubators”* (Adopted Amendment 1:1996 to IEC 601-2-19 (1990), without modification) . . . . . \$85

**CAN/CSA-C22.2 No. 601.2.20A-01 (bilingual)**  
*Amendment 1:2001 to CAN/CSA-C22.2 No. 601.2.20-92, “Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Transport Incubators”* (Adopted Amendment 1:1996 to IEC 601-2-20 (1990), without modification) . . . . . \$95

**CAN/CSA-C22.2 No. 601.2.21A-01 (bilingual)**  
*Amendment 1:2001 to CAN/CSA-C22.2 No. 601.2.21-98, “Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Infant Radiant Warmers”* (Adopted Amendment 1:1996 to IEC 601-2-21 (1994), without modification) . . . . . \$85



**CAN/CSA-C22.2 No. 601.2.31A-01**  
*Amendment 1:2001 to CAN/CSA-C22.2 No. 601.2.31-98, "Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of External Cardiac Pacemakers With Internal Power Source"* (Adopted Amendment 1:1998 to IEC 601-2-31 (1994), without modification) . . . . . \$95

Les quatre normes qui suivent ont été élaborées par la Commission Électrotechnique Internationale (CEI) et adoptées par CSA International.

## Nouvelles parutions en français

**CAN/CSA-ISO 10993-1-01, 2<sup>e</sup> édition**  
*Évaluation biologique des dispositifs médicaux—Partie 1 : Évaluation et essais* (norme ISO 10993-1:1997 adoptée, deuxième édition) . . . . . 50 \$

Cette norme décrit :

- a) les principes généraux sur lesquels repose l'évaluation biologique des dispositifs médicaux ;
- b) la classification de dispositifs, basée sur la nature et la durée de leur contact avec le corps humain ;
- c) le choix des essais appropriés.

**CAN/CSA-ISO 10993-5-01, 2<sup>e</sup> édition**  
*Évaluation biologique des dispositifs médicaux—Partie 5 : Essais concernant la cytotoxicité in vitro* (norme ISO 10993-5:1999 adoptée, deuxième édition) . . . . . 40 \$

Cette norme décrit des méthodes d'essai pour mesurer la cytotoxicité in vitro des dispositifs médicaux.

Ces méthodes spécifient l'incubation de cellules en culture soit directement, soit par diffusion a) avec des extraits du dispositif, et/ou b) en contact direct avec le dispositif. Ces méthodes sont destinées à déterminer la réponse biologique de cellules de mammifères in vitro, à l'aide de paramètres biologiques appropriés.

**M421-00, 3<sup>e</sup> édition**  
*Utilisation de l'électricité dans les mines* . . . . . 75 \$

Cette norme établit les exigences minimales relatives aux travaux d'électricité et à l'appareillage électrique fonctionnant, ou destiné à fonctionner, dans les mines et les carrières.

**CAN/CSA-M3776-00, 1<sup>re</sup> édition**  
*Tracteurs agricoles—Ancrages pour ceintures de sécurité* (norme ISO 3776:1989 adoptée) . . . . . 30 \$

Cette norme fixe les spécifications de l'emplacement des ancrages de ceintures pelviennes pour conducteurs de tracteurs agricoles équipés d'un bâti de protection, la force à laquelle ils doivent être capables de résister et les essais auxquels ils doivent être soumis.

**CAN/CSA-C22.2 n° 601.2.17A-01 (bilingue)**  
*Amendement 1:2001 de CAN/CSA-C22.2 n° 601.2.17-94, Appareils électromédicaux—Partie 2 : Règles particulières de sécurité des appareils projecteurs de sources radioactives automatiques télécommandés utilisés en radiothérapie par rayonnement gamma* (norme CEI 601-2-17 (1989) adoptée, Amendement 1:1996, sans modification) . . . . . 85 \$

**CAN/CSA-C22.2 n° 601.2.19A-01 (bilingue)**  
*Amendement 1:2001 de CAN/CSA-C22.2 n° 601.2.19-92, Appareils électromédicaux—Partie 2 : Règles particulières de sécurité des incubateurs pour bébés* (norme CEI 601-2-19 (1990) adoptée, Amendement 1:1996, sans modification) . . . . . 85 \$

**CAN/CSA-C22.2 n° 601.2.20A-01 (bilingue)**  
*Amendement 1:2001 de CAN/CSA-C22.2 n° 601.2.20-92, Appareils électromédicaux—Partie 2 : Règles particulières de sécurité des incubateurs de transport* (norme CEI 601-2-20 (1990) adoptée, Amendement 1:1996, sans modification) . . . . . 95 \$

**CAN/CSA-C22.2 n° 601.2.21A-01 (bilingue)**  
*Amendement 1:2001 de CAN/CSA-C22.2 n° 601.2.21-98, Appareils électromédicaux—Partie 2 : Règles particulières de sécurité pour les incubateurs radiants pour nouveau-nés* (norme CEI 601-2-21 (1994) adoptée, Amendement 1:1996, sans modification) . . . . . 85 \$

## Drafts

**Please note:** Public comments about draft standards and proposed amendments listed in this issue are due by April 26, 2001.

To receive copies of the following draft standard, or to offer comments, contact Nancy Bestic at 416-747-2710 or [nancy.bestic@csa-international.org](mailto:nancy.bestic@csa-international.org):

- **Z317.11, 2nd edition**  
*Area Measurement for Health Care Facilities*

To receive copies of the following draft standard, or to offer comments, contact Andre Wisaksana at 416-747-4242 or [andre.wisaksana@csa-international.org](mailto:andre.wisaksana@csa-international.org):

- **Z317.1-99, proposed amendment**  
*Special Requirements for Plumbing*  
 Proposed amendment to Clause 1.3.



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## Proposed New Projects

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For more information about the proposed development of the following new publication, contact Ian Brodie at 416-747-2670 or [ian.brodie@csa-international.org](mailto:ian.brodie@csa-international.org):

- **PLUS 1159, 1st edition**  
*Customer Service Guide for Persons with Disabilities*

For more information about the proposed development of the following new standard, contact Jeffrey Kraegel at 416-747-2249 or [jeffrey.kraegel@csa-international.org](mailto:jeffrey.kraegel@csa-international.org):

- **Z305.8, 1st edition**  
*Medical Supply Units*

For more information about the proposed development of the following new handbook, contact Steve Paniri at 416-747-4118 or [steve.paniri@csa-international.org](mailto:steve.paniri@csa-international.org):

- **B44 Handbook, 1st edition**  
*Safety Code for Elevators Handbook*

For more information about the proposed development of the following new editions, contact Dave Shanahan at 416-747-2586 or [dave.shanahan@csa-international.org](mailto:dave.shanahan@csa-international.org):

- **Z275.1, 4th edition**  
*Hyperbaric Facilities*
- **Z275.2, 4th edition**  
*Occupational Safety Code for Diving Operations*
- **Z275.4, 2nd edition**  
*Competency Standard for Diving Operations*

For more information about the proposed development of the following new edition, contact Andre Wisaksana at 416-747-4242 or [andre.wisaksana@csa-international.org](mailto:andre.wisaksana@csa-international.org):

- **Z318, 2nd edition**  
*Commissioning of Health Care Facilities*

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## Reaffirmed Standards

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CAN/CSA-B651-95 (R2001)  
*Barrier-Free Design*

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## Certification Notices

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Please note: ► Notices marked with an arrowhead are new in this issue.

Effective Date	Subject	Title
July 30, 2001	Publication of CSA International's Z94.3-99 (5th edition), <i>Industrial Eye and Face Protectors</i> .	Occupational Health and Safety Products No. 37
January 1, 2003	Publication of standards on <i>Medical Electrical Equipment</i> : CAN/CSA-C22.2 No. 601.1.3-98, No. 601.1.1S1-94, and No. 601.2.21, .23, .27, .31, .32, .33, and .34. (Products may be evaluated to these standards now.)	Health Care Equipment No. 11