

National Standard of Canada
CAN/CSA-ISO 13488-98
 (ISO 13488:1996)

International Standard ISO 13488:1996 (first edition, 1996-12-15) has been adopted without modification as CSA Standard CAN/CSA-ISO 13488-98, which has been approved as a National Standard of Canada by the Standards Council of Canada.

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**Quality systems — Medical devices —
 Particular requirements for the application
 of ISO 9002**

*Systèmes qualité — Dispositifs médicaux — Exigences particulières
 relatives à l'application de l'ISO 9002*



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L'Association canadienne de normalisation (CSA), sous les auspices de laquelle cette Norme nationale a été préparée, a reçu ses lettres patentes en 1919 et son accréditation au sein du Système de normes nationales par le Conseil canadien des normes en 1973. Association d'affiliation libre, sans but lucratif ni pouvoir de réglementation, elle se consacre à l'élaboration de normes et à la certification.

Les normes CSA reflètent le consensus de producteurs et d'utilisateurs de partout au pays, au nombre desquels se trouvent des fabricants, des consommateurs, des détaillants et des représentants de syndicats, de corps professionnels et d'agences gouvernementales. L'utilisation des normes CSA est très répandue dans l'industrie et le commerce, et leur adoption à divers ordres de législation, tant municipal et provincial que fédéral, est chose courante, particulièrement dans les domaines de la santé, de la sécurité, du bâtiment, de la construction et de l'environnement.

Les Canadiens d'un bout à l'autre du pays témoignent de leur appui au travail de normalisation mené par la CSA en participant bénévolement aux travaux des comités de la CSA et en appuyant ses objectifs par leurs cotisations de membres de soutien. Les quelque 7000 volontaires faisant partie des comités et les 2000 membres de soutien constituent l'ensemble des membres de la CSA parmi lesquels ses administrateurs sont choisis. Les cotisations des membres de soutien représentent une source importante de revenu pour les services de soutien à la normalisation volontaire.

L'Association offre des services de certification et de mise à l'essai qui appuient et complètent ses activités dans le domaine de l'élaboration de normes. De manière à assurer l'intégrité de son processus de certification, l'Association procède de façon régulière et continue à l'examen et à l'inspection des produits portant la marque CSA.

Outre son siège social et ses laboratoires à Etobicoke, la CSA possède des bureaux régionaux dans des centres vitaux partout au Canada, de même que des agences d'inspection et d'essai dans huit pays. Depuis 1919, l'Association a parfait les connaissances techniques qui lui permettent de remplir sa mission d'entreprise, à savoir la CSA est un organisme de services indépendant dont la mission est d'offrir une tribune libre et efficace pour la réalisation d'activités facilitant l'échange de biens et de services par l'intermédiaire de services de normalisation de certification et autres, pour répondre aux besoins de nos clients, tant à l'échelle nationale qu'internationale.

The Canadian Standards Association (CSA), under whose auspices this National Standard has been produced, was chartered in 1919 and accredited by the Standards Council of Canada to the National Standards system in 1973. It is a not-for-profit, nonstatutory, voluntary membership association engaged in standards development and certification activities. CSA standards reflect a national consensus of producers and users — including manufacturers, consumers, retailers, unions and professional organizations, and governmental agencies. The standards are used widely by industry and commerce and often adopted by municipal, provincial, and federal governments in their regulations, particularly in the fields of health, safety, building and construction, and the environment.

Individuals, companies, and associations across Canada indicate their support for CSA's standards development by volunteering their time and skills to CSA Committee work and supporting the Association's objectives through sustaining memberships. The more than 7000 committee volunteers and the 2000 sustaining memberships together form CSA's total membership from which its Directors are chosen. Sustaining memberships represent a major source of income for CSA's standards development activities.

The Association offers certification and testing services in support of and as an extension to its standards development activities. To ensure the integrity of its certification process, the Association regularly and continually audits and inspects products that bear the CSA Mark.

In addition to its head office and laboratory complex in Etobicoke, CSA has regional branch offices in major centres across Canada and inspection and testing agencies in eight countries. Since 1919, the Association has developed the necessary expertise to meet its corporate mission: CSA is an independent service organization whose mission is to provide an open and effective forum for activities facilitating the exchange of goods and services through the use of standards, certification and related services to meet national and international needs.

Pour plus amples renseignements sur les services de la CSA, s'adresser à
Association canadienne de normalisation

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• For further information on CSA services, write to

• Canadian Standards Association

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Le Conseil canadien des normes est l'organisme de coordination du Système de normes nationales, une fédération d'organismes indépendants et autonomes qui travaillent au développement et à l'amélioration de la normalisation volontaire dans l'intérêt national.

Les principaux buts du Conseil sont d'encourager et de promouvoir la normalisation volontaire comme moyen d'améliorer l'économie nationale, d'améliorer la santé, la sécurité et le bien-être du public, d'aider et de protéger le consommateur, de faciliter le commerce national et international et de favoriser la coopération internationale dans le domaine de la normalisation.

Une Norme nationale du Canada est une norme, approuvée par le Conseil canadien des normes, qui reflète une entente raisonnable parmi les points de vue d'un certain nombre de personnes compétentes dont les intérêts réunis forment, au degré le plus élevé possible, une représentation équilibrée des producteurs, utilisateurs, consommateurs et autres personnes intéressées, selon le domaine envisagé. Il s'agit généralement d'une norme qui peut apporter une contribution appréciable, en temps opportun, à l'intérêt national.

L'approbation d'une norme en tant que Norme nationale du Canada indique qu'elle est conforme aux méthodes et critères établis par le Conseil canadien des normes.

L'approbation ne porte pas sur l'aspect technique de la norme; cet aspect demeure la responsabilité de l'organisme rédacteur de normes accrédité.

Il est recommandé aux personnes qui ont besoin de normes de se servir des Normes nationales du Canada lorsque la chose est possible. Ces normes font l'objet d'examen périodiques; c'est pourquoi il est recommandé aux utilisateurs de se procurer l'édition la plus récente de la norme auprès de l'organisme qui l'a préparée.

The Standards Council of Canada is the coordinating body of the National Standards system, a federation of independent, autonomous organizations working towards the further development and improvement of voluntary standardization in the national interest.

The principal objects of the Council are to foster and promote voluntary standardization as a means of advancing the national economy, benefiting the health, safety, and welfare of the public, assisting and protecting the consumer, facilitating domestic and international trade, and furthering international cooperation in the field of standards.

A National Standard of Canada is a standard which has been approved by the Standards Council of Canada and one which reflects a reasonable agreement among the views of a number of capable individuals whose collective interests provide to the greatest practicable extent a balance of representation of producers, users, consumers, and others with relevant interests, as may be appropriate to the subject in hand. It normally is a standard which is capable of making a significant and timely contribution to the national interest.

Approval of a standard as a National Standard of Canada indicates that a standard conforms to the criteria and procedures established by the Standards Council of Canada.

Approval does not refer to the technical content of the standard; this remains the continuing responsibility of the accredited standards-development organization.

Those who have a need to apply standards are encouraged to use National Standards of Canada whenever practicable. These standards are subject to periodic review; therefore, users are cautioned to obtain the latest edition from the organization preparing the standard.

La responsabilité d'approuver les Normes nationales du Canada incombe au
Conseil canadien des normes

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• The responsibility for approving National Standards of Canada rests with the

• Standards Council of Canada

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Les normes nationales du Canada sont publiées en versions française et anglaise.
National Standards of Canada are published in English and French.

Bien que le but premier visé par cette norme soit énoncé sous sa rubrique Domaine d'application, il est important de retenir qu'il incombe à l'utilisateur de juger si la norme convient à ses besoins particuliers.

Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the user to judge its suitability for their particular purpose.

CAN/CSA-ISO 13488-98

Quality systems — Medical devices — Particular requirements for the application of ISO 9002

CSA Preface

This is the first edition of CSA Standard CAN/CSA-ISO 13488, *Quality devices — Medical devices — Particular requirements for the application of ISO 9002*, which is an adoption without modification of the identically titled ISO (International Organization for Standardization) Standard 13488:1996 (first edition, 1996-12-15), developed by the ISO Technical Committee ISO/TC 210.

This Standard was reviewed for Canadian adoption by the CSA Technical Committee on Quality Management and General Aspects for Medical Devices, under the jurisdiction of the Strategic Steering Committee on Health Care Technology, and has been formally approved by the Technical Committee. A list of the members of these Committees is available upon request. This Standard has been approved as a National Standard of Canada by the Standards Council of Canada.

January 1998

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January 1998

INTERNATIONAL STANDARD

**ISO
13488**

First edition
1996-12-15

Quality systems — Medical devices — Particular requirements for the application of ISO 9002

*Systèmes qualité — Dispositifs médicaux — Exigences particulières
relatives à l'application de l'ISO 9002*



Content	Page
1 Scope	1
2 Normative references	1
3 Definitions	1
4 Quality system requirements	3
4.1 Management responsibility	3
4.2 Quality system	3
4.3 Contract review	3
4.4 Design control	3
4.5 Document and data control	4
4.6 Purchasing	4
4.7 Control of customer-supplied product	4
4.8 Product identification and traceability	4
4.9 Process control	5
4.10 Inspection and testing	6
4.11 Control of inspection, measuring and test equipment	7
4.12 Inspection and test status	7
4.13 Control of nonconforming product	7
4.14 Corrective and preventive action	7
4.15 Handling, storage, packaging, preservation and delivery ..	8
4.16 Control of quality records	9
4.17 Internal quality audits	9
4.18 Training	9
4.19 Servicing	9
4.20 Statistical techniques	9

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 13488 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.