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# Clinical laboratory testing and *in vitro* diagnostic test systems — *In vitro* diagnostic medical devices for professional use — Summary of regulatory requirements for information supplied by the manufacturer

*Essais cliniques de laboratoire et systèmes d'essai de diagnostic in vitro — Dispositifs de diagnostic médical in vitro à usage professionnel — Résumé des exigences de régulation pour les informations fournies par le fabricant*

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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
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## Foreword

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The main task of technical committees is to prepare International Standards. 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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard (“state of the art”, for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 18112 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

# Introduction

This Technical Report summarizes the current labelling requirements of Canada, the EU, Japan and the US for *in vitro* diagnostic (IVD) medical devices for professional use. It also includes, for comparison, proposed guidance from the Global Harmonization Task Force (GHTF) and recommendations from the *In vitro* Diagnostic Device Working Group of the Australian National Coordinating Committee for Therapeutic Goods. This technical report is intended for use in identifying gaps between existing CEN documents and country regulations, and the best solution for these gaps; it is one of a multi-part series of documents that is described in ISO/TC 212 New Work Item Proposal N96-Rev.1.

This summary provides regulatory authorities, manufacturers and users of IVD medical devices with an opportunity to compare existing and proposed labelling requirements from a cross-section of the regulated world, so significant differences can be recognized and addressed. A preliminary summary has been provided to the GHTF for use in identifying opportunities for harmonizing IVD labelling requirements. This report was prepared to assist ISO/TC 212 in developing international standards to support the harmonization efforts.

While significant benefits from harmonized labelling requirements are anticipated, this Technical Report does not evaluate the merits of one regulatory approach over another. Rather, it presents existing requirements factually, so organizations charged with developing harmonized regulations and standards can decide which requirements are essential for promoting safe and effective IVD medical devices.

This summary is only a snapshot in time, while the regulatory environment is dynamic and changing. Australia and Japan are developing new regulatory frameworks for IVD medical devices. The United States is revisiting its position on graphical symbols. European countries continue to debate which languages are necessary on limited label space.

Manufacturers are cautioned that this Technical Report does not substitute for official published labelling requirements. Although efforts were made to verify the accuracy of the information at this point in time, regulatory requirements are subject to interpretation and change. Specific guidance may be in place in some countries that interprets, explains, clarifies, amplifies or even modifies the requirements. Manufacturers are responsible for knowing, understanding and complying with the official regulatory requirements in each country in which their product is sold.