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Quality systems — Medical devices — Particular requirements for the application of ISO 9001

Systèmes qualité — Dispositifs médicaux — Exigences particulières relatives à l'application de l'ISO 9001



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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 13485 was prepared by Technical Committee ISO/TC 210, Quality management and corresponding general aspects for medical devices.