

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**Application of risk management for IT-networks incorporating medical devices –
Part 1: Safety, effectiveness and security in the implementation and use of
connected medical devices or connected health software**

**Application de la gestion des risques aux réseaux des technologies de
l'information contenant des dispositifs médicaux –
Partie 1: Sûreté, efficacité et sécurité dans la mise en œuvre et l'utilisation des
dispositifs médicaux connectés ou des logiciels de santé connectés**

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**APPLICATION OF RISK MANAGEMENT FOR IT-NETWORKS
INCORPORATING MEDICAL DEVICES –****Part 1: Safety, effectiveness and security in the implementation and use
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FOREWORD

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It is published as a double logo standard.

This second edition cancels and replaces the first edition published in 2010. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) structure changed to better align with ISO 31000;
- b) establishment of requirements for an ORGANIZATION in the application of RISK MANAGEMENT;

- c) communication of the value, intention and purpose of RISK MANAGEMENT through principles that support preservation of the KEY PROPERTIES during the implementation and use of connected HEALTH SOFTWARE and/or HEALTH IT SYSTEMS.

The text of this document is based on the following documents:

FDIS	Report on voting
62A/1434/FDIS	62A/1448/RVD

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT OR AS NOTED ARE PRINTED IN SMALL CAPITALS.

In referring to the structure of this document, the term

- “clause” means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 5 includes subclauses 5.1, 5.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 5.1, 5.2 and 5.3 are all subclauses of Clause 5).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

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Future standards in this series will carry the new general title as cited above. Titles of existing standards in this series will be updated at the time of the next edition.