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management Committe document (EN ISO) has been prepared by Technical Committee ISO/TC "Quality CEN/CLC/JTC secretariat and corresponding“Quality held by NEN. management aspects for corresponding devices" in collaboration Technical This European withdrawn Attention is drawn (6) Har monised standards EN +A and EN ISO, as amended by EN ISO A, satisfy the requirements which they aim to cover and which are set out in Regulation (EU) It is therefore appropr iate to publish the references of har monised standards EN +A and EN ISO and of its The European standard EN ISO with its amendment A is finally cited in the Official Journal of the European Union (OJEU) as a harmonized standard in support of the European regulations (EU) for medical devices and (EU) for in vitro diagnostic medical devices This document could be used as guidance in developing and maintaining a risk management process for other products that are not necessarily medical devices in some jurisdictions and for suppliers and other parties involved in the medical device life cycle. This document deals with processes for managing risks associated with medical devices This document specifies terminology, principles and a process for risk management of medical devices, including software as a medical device and in vitro diagnostic medical The method for the evaluation of the overall residual risk and the criteria for its acceptability are required to be defined in the risk management plan. The method can include This European Standard EN ISO /A was adopted as Luxembourgish Standard ILNAS-EN ISO /A Every interested party, which is BS EN ISO +A Medical devices. The requirements of this document are applicable to all phases of the life European foreword. Application of risk management to medical devices (British Standard)Documents sold on the ANSI store are in The European standard EN ISO with its amendment A is finally cited in the Official Journal of the European Union (OJEU) as a harmonized standard in support The process described in this document intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

Difficulté **Très facile** | Durée **242 jour(s)**

Catégories **Énergie, Maison, Musique & Sons, Recyclage & Upcycling, Science & Biologie** | Coût **297 USD ($)**

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