The article seeks to design a risk management framework at the Sterilization Unit in the San Jose Hospital according to the ISO 31000 guidelines as outcome of a research project between the Catholic University of Colombia and the Fundacion Universitaria de Ciencias de la Salud. This proposal can generate knowledge to improve the making-decisions into the medical processes to achieve the Patient Safety Policy. In addition, Risk Management is linked with the Patient Safety Policy, laws and normative in health sector, but in the literature review realized in Scopus, Science Direct and ISI Web of Knowledge databases risks and sterilization are not linked with Quality Management System and Knowledge Management in research publications. Furthermore, several research and review articles have a lot of information about technical information while the need on holistic approach is not appear in these databases. The methodological design was structured in accordance to the ISO 31000 guidelines and legal normative in a Colombian sterilization unit that realize sterilization by autoclave, hydrogen peroxide and ethylene oxide and it is processing 200 packages daily approximately. On the one hand, the risk management framework has seven foundations and five risk criteria to identify and evaluate them. On the other hand, the risk management framework had applied into sterilization processes and we identified and evaluated 15 risks on 14 sub-processes. Risk management began in washing and disinfection process and finalize in storage packets. In addition, sterilization risks have several impacts on organizational objectives and key indicators. Risks analysis tools must be included to generate scenarios and reports to take decisions. People who works in sterilization unit must use lessons learned to incorporate it in the risk management framework. Quality Management System for Medical Devices is an opportunity to improve the performance on the sterilization processes.