



ISO/TR 18965

Medical devices — Examples of the application of the risk management process to cardiac valve replacement and repair systems

Dispositifs médicaux — Exemples d'application du processus de gestion des risques aux systèmes de remplacement et de réparation des valves cardiaques

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Risk management is the underlying foundation of the product development process and should be considered throughout all phases of the product development cycle. This document provides guidance to assist manufacturers on the application of the risk management process, as described in ISO 13485 and ISO 14971, to cardiac valve replacement and repair systems. [Figure 1](#) demonstrates the relationship between the risk and device standards as well as the applicable Technical Reports that support the risk management process.