6.4.2	For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.	No	Sterile devices
7.5.5	The organization shall maintain records of the sterilization process parameters used for each sterilization batch (see 4.2.5). Sterilization records shall be traceable to each production batch of medical devices.	No	Sterile devices
7.5.7	The organization shall document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems. Processes for sterilization and sterile barrier systems shall be validated prior to implementation and following product or process changes, as appropriate. Records of the results and, conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5). NOTE Further information can be found in ISO 11607-1 and ISO 11607-2.	No	Sterile devices