

ISO 13408-5:2006-11 (E)

Aseptic processing of health care products - Part 5: Sterilization in place

Contents		Page
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Quality system elements	3
4.1	General	3
4.2	Management responsibility	3
4.3	Design control	3
4.4	Measuring instruments and measuring systems	3
5	Process and equipment characterization	4
5.1	General concepts	4
5.2	Effectiveness of sterilization in place (SIP)	4
5.3	Equipment	4
6	Sterilizing agent characterization	6
6.1	Selection of sterilizing agent(s)	6
6.2	Quality of sterilizing agent(s)	6
6.3	Safety and the environment	6
7	SIP process	6
7.1	Process parameters	6
7.2	Cycle development	7
8	Validation	7
8.1	Validation protocol	7
8.2	Design qualification	7
8.3	Installation qualification	7
8.4	Operational qualification	8
8.5	Performance qualification	8
8.6	Review and approval of validation	10
8.7	Requalification	10
9	Routine monitoring and control	10
9.1	SIP process control	10
9.2	Procedures	10
9.3	SIP process records	11
9.4	Change control	11
9.5	Maintenance of equipment	11
10	Personnel training	11
	Annex A (informative) Steam sterilization in place	12
	Bibliography	14