Table 17-7 International Standards Organization (ISO) Technical Committee (TC) 198 Standards for Sterilization of Health Care Products

ISO document reference	Brief description of reference
Standards	
ISO 11134:1994	Sterilization of health care products—requirements for validation and routine control—industrial moist heat sterilization
ISO 11135:1994	Medical devices—validation and routine control of ethylene oxide sterilization
ISO 11135:1994/Cor 1:1994	
ISO 11137:1995	Sterilization of health care products—requirements for validation and routine control—radiation sterilization
ISO 11137:1995/Cor 1:1997	
ISO 11137:1995/Amd 1:2001	Selection of items for dose setting
ISO 11138–1:1994	Sterilization of health care products—biological indicators–Part 1: General
ISO 11138–2:1994	Sterilization of health care products—biological indicators–Part 2: biological indicators for ethylene oxide sterilization
ISO 11138–3:1995	Sterilization of health care products—biological indicators—part 3: biological indicators for moist heat sterilization
ISO/TS 11139:2001	Sterilization of health care products—vocabulary
ISO 11140–1:1995	Sterilization of health care products—chemical indicators—Part 1: general requirements
ISO 11140–1:1995/Amd 1:1998	
ISO 11140–2:1998	Sterilization of health care products—chemical indicators—Part 2: test equipment and methods
ISO 11140–3:2000	Sterilization of health care products—chemical indicators—Part 3: class 2 indicators for steam penetration test sheets
ISO 11140–4:2001	Sterilization of health care products—chemical indicators—Part 4: class 2 indicators for steam penetration test packs
ISO 11140–5:2000	Sterilization of health care products—chemical indicators—Part 5: class 2 indicators for air removal test sheets and packs
ISO 11607:2003	Packaging for terminally sterilized medical devices
ISO 11737–1:1995	Sterilization of medical devices—microbiological methods–Part 1: estimation of population of microorganisms on products
ISO 11737–2:1998	Sterilization of medical devices—microbiological methods—Part 2: tests of sterility performed in the validation of a sterilization process
ISO 11737–3:2004	Sterilization of medical devices—microbiological methods—Part 3: guidance on evaluation and interpretation of bioburden data
ISO 13408–1:1998	Aseptic processing of health care products—Part 1: general requirements
ISO 13408–2:2003	Aseptic processing of health care products—Part 2: filtration
ISO 13408–6:2005	Aseptic processing of health care products—Part 6: isolator systems
ISO/TS 13409:2002	Sterilization of health care products—radiation sterilization—substantiation of 25 kG as a sterilization dose for small or infrequent production batches
ISO 13683:1997	Sterilization of health care products—requirements for validation and routine control of moist heat sterilization in health care facilities
ISO 14160:1998	Sterilization of single-use medical devices incorporating materials of animal origin—validation and routine control of sterilization by liquid chemical sterilants
ISO 14161:2000	Sterilization of health care products—biological indicators—guidance for the selection, use and interpretation of results
ISO 14937:2000	Sterilization of health care products—general requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices
ISO/TS 15843:2000	Sterilization of health care products—radiation sterilization—product families and sampling plans for verification dose experiments and sterilization dose audits, and frequency of sterilization dose audits
ISO/TR 15844:1998	Sterilization of health care products—radiation sterilization—selection of sterilization dose for a single production batch
ISO 15882:2003	Sterilization of health care products—chemical indicators—guidance for selection, use and interpretation of results
ISO 17664:2004	Sterilization of medical devices—information to be provided by the manufacturer for the processing of resterilizable medical

Source: From Ref. 11.