

Govern.order 181/2001 Coll., as amended	by means of which Technical Requirements for Medical Technology are Defined
Act no. 123/2000 Coll.	on medical devices
Act no. 102/2001	on general safety of devices
CSN (Czech Standard) EN ISO 9001:95	Quality systems – Models of quality securing during design, development, production, installation and service
CSN EN 46001:98	Quality systems – Medical devices – Special requirements for use EN ISO 9001
CSN EN ISO 13 485:2001	Quality systems – Medical devices - Requirements for use CSN EN 46001:96 Quality systems – Medical devices – requirements for use CSN EN 46001:96
CSN EN ISO 13 485:2001	Quality systems – Medical devices - Requirements for use CSN EN 46001:96 Quality systems – Medical devices – requirements for use CSN EN 46001:96
CSN EN 1441:99	Medical Technology Means – Risk analysis
CSN EN 1041:98	Information of manufacturers of medical devices
CSN EN 552:98	Sterilisation of medical devices – Validation and continuous checks of sterilisation by radiation
CSN EN 556:98	Sterilisation of medical devices – Requirements for packed sterilised medical devices marked as sterile
CSN EN ISO 10993-1:99	Biological assessment of medical devices – Part 1: assessment and testing
CSN EN ISO 10993-1:98	Biological assessment of medical devices – Part 10: irritability testing
CSN EN 1174-1:98	Sterilisation of medical devices – Estimate of micro-organism population on the device – Part 1: requirements
CSN EN 1174-2:98	Sterilisation of medical devices – Estimate of micro-organism population on the device – Part 2: instructions
CSN EN 1174-3:98	Sterilisation of medical devices – Estimate of micro-organism population on the device – Part 3: guidelines for microbiologic method procedures
ČL 97	Czech pharmacopoeia 97
CSN EN 11 137	Part Table – Relation of radiation dose and biopollution of the device
	Standards, technical documentation and SJ documentation mentioned in TF and the final report of the clinical assessment