13485	Content	*820*	*Content*	Comparision
4	quality management system	/		/
4.1	general requirements	*820.186*	*quality system record*	related
4.2	document requirements	/		/
4.2.1	general			Different
4.2.2	quality manual			Different
4.2.3	MD file	*820.181*	*device master record*	similar
4.2.4	control of documents	*820.40*	*document controls*	similar
4.2.5	control of records	*820.180*	*general requirements (records)*	similar
5	mannagement responsibility	/		/
5.1	management commitment			Different
5.2	customer focus			Different
5.3	quality policy	*820.20 a*		
5.4	planning			Different
5.5	responsibility, authority and communication	/		/
5.5.1	responsibility and authority	*820.20*	*management responsibility*	similar
5.5.2	management representative	*820.20*		similar
5.5.3	internal communication			Different
5.6	management review	*820.20*		similar
6	resource management	*820.20*		similar
6.1	provision of resources			Different
6.2	human resources	*820.25*	*personnel*	similar
6.3	infrastructure	*820.70 f,g*		similar
6.4.1	work environment	*820.70 c,d*		similar
6.4.2	contamination control	*820.70 e*		similar
7	Product realization	/		/
7.1	planning of product realization	*820.20 d*		similar
7.2	customer-related processes	/		/
7.2.1	determination of requirements related to product			Different
7.2.2	review of requiements related to product			Different
7.2.3	communicaton			Different
7.3	Design and development	/		/
7.3.1	general	*820.30*	*design controls*	similar
7.3.2	planning	*820.30 b*		similar
7.3.3	inputs	*820.30 c*		similar
7.3.4	outputs	*820.30 d*		similar
7.3.5	review	*820.30 e*		similar
7.3.6	verification	*820.30 f*		similar
7.3.7	validation	*820.30 g*		similar
7.3.8	transfer	*820.30 h*		similar
7.3.9	control of changes	*820.30 i*		similar
7.3.10	files	*820.30 j*	*design history file (DHF)*	similar
		820.184	*device history record (DHR)*	similar
7.4	purchasing	*820.50*	*purchasing controls*	similar
7.4.1	purchasing process	*820.50 a*		similar
7.4.2	purchasing information	*820.50 b*		similar
7.4.3	verification of purchased product	*820.8 b*	*receiving, in-process, and finished device acceptance*	similar
7.5	production and service provision	/		
7.5.1	control of production and service provision	*820.70 a*	*production and process controls - general*	similar
7.5.2	cleaniness of product	*820.70 e*		related
7.5.3	installation activities	*820.170*	*installation*	similar
7.5.4	servicing activities	*820.200*	*serviving*	similar
7.5.5	particular requirements for sterile medical devices			Different
7.5.6	validation of processes for production and service provision	*820.70 b*	*production and process changes*	similar
		820.70 i	*automated processes*	similar
		820.75	*process validation*	similar
7.5.7	particular requirements for validation of processes for sterilization and sterile barrier systems	*820.75*	*process validation*	similar
7.5.8	identification	*820.60*	*identification*	similar
		820.86	*acceptance status*	similar
7.5.9	traceability	*820.65*		similar
7.5.10	customer property			Different
7.5.11	preservation of product	*820.130*	*device packaging*	similar
		820.140	*handling*	similar
		820.150	*storage*	similar
		820.160	*distribution*	similar
7.6	control of monitoring and measuring equipment	*820.72*	*inspection,measuring,and test equipment*	similar
8	Measurement,analysis and improvement	/		/
8.1	general	/		/
8.2	Monitoring and measurement	/		/
8.2.1	feedback			Different
8.2.2	complain handling	*820.198*	*complaint files*	similar
8.2.3	reporting to regulatory authorities	*820.198*		similar
8.2.4	internal audit	*820.22*	*quality audit*	similar
8.2.5	monitoring and measurement of processes			Different
8.2.6	monitoring and measurement of product	*820.80 c,d,e*	*receiving, in-process, and finished device acceptance*	similar
8.3	control of nonconforming product	*820.9*	*nonconforming product*	similar
8.3.1	control of nonconforming product-general	*820.90 a*		similar
8.3.2	actions in response to nonconforming product detected before delivery	*820.90 b*		similar
8.3.3	actions in response to nonconforming product detected after delivery			Different
8.3.4	rework	*820.90 b*		similar
8.4	analysis of data	*820.250*	*statistical techniques*	related
8.5	Improvement	/		/
8.5.1	general			/
8.5.2	correctiv		*ve action*	similar
8.5.3	preventiv			similar
				Different
				Different