I 3 CONSULTING

MANDATORY PROCEDURES

ISO 13485 & 21 CFR 820

#	Clause	Name	Remarks
1.	**4.1**	Outsourcing process	
2.	**4.2.3**	Control of documents	
3.	**4.2.4**	Control of records	
4.	**5.6**	Management Review	Optional
5.	**6.2.2**	Training	Optional
6.	**6.3**	Maintenance Activities	
7.	**6.4**	Health, cleanliness and clothing	
8.	**6.4**	Work environment monitoring and control	
9.	**6.4**	Control of contamination	
10.	**7.1**	Risk Management	
11.	**7.2**	Contract Review	Optional
12.	**7.3.1**	Design and development	
13.	**7.4.1**	Purchasing process	
14.	**7.5.1.2.1**	Product cleanliness	
15.	**7.5.1.2.2**	Installation activities	
16.	**7.5.1.2.3**	Servicing activities	
17.	**7.5.2.1**	Validation of the application of the computer S/W	
18.	**7.5.2.2**	Sterilization process validation	
19.	**7.5.3.1**	Product identification	
20.	**7.5.3.1**	Product return identification from normal production	
21.	**7.5.3.2**	Product traceability	
22.	**7.5.5**	Product preservation	
23.	**7.5.5**	Control of limited shelf life products	
24.	**7.6**	Control of monitoring and measuring equipment	
25.	**8.2.1**	Feedback system (including customer complaint)	
26.	**8.2.1**	Post-Market surveillance	CE Certification only
27.	**8.2.1**	Post – Market Clinical follow-up	CE Certification only
28.	**8.2.1**	Clinical evaluation	CE Certification only
29.	**8.2.2**	Internal audit	
30.	**8.2.4.1**	Monitoring and measurement of product	
31.	**8.3**	Control of nonconforming product	
32.	**8.4**	Analysis of data	
33.	**8.5.1**	Advisory notice	
34.	**8.5.1**	Vigilance system	CE Certification only
35.	**8.5.1**	Handling of customer complaints	
36.	**8.5.2**	CAPA	
37.		Medical Device Reporting	21 CFR 820