

21 CFR Part 11 Chapter	EU Annex 11 section	21 CFR Part 211 section	21 CFR Part 820 section	SOC 2 Type 2 control ID
21 CFR 11.10(a)	4-Validation	211.68 211.100(a), (b). 211.194(d)	820.70(i) 820.30(g) 820.170	CC2.1, CC2.3, CC3.1, CC3.4, CC5.1, CC6.8, CC7.1, CC7.2, CC7.5, CC8.1, CC9.1, CC9.2, A1.1
21 CFR 11.10(b)	8.1-Printouts	211.180(c)	820.40 820.180	CC6.1, CC6.2, CC6.3, CC6.4, CC6.6, CC6.7, CC6.8, CC7.1, CC7.2, CC7.4, CC7.5, CC8.1, A1.1, A1.2
21 CFR 11.10(c)	17-Archiving, 12-Security 7-Data Storage	211.68(b)	820.20 820.40 820.180	CC2.2, CC2.3, CC6.1, CC6.7, CC7.1, CC7.2, CC7.4, CC7.5, A1.1, A1.2, A1.3, C1.1
21 CFR 11.10(d)	7.1- secured and accessible 10- Change and Configuration Management 12.1-Security, physical/logical	211.68	820.30(i) 820.70(i) 820.40	CC5.2, CC6.1, CC6.2, CC6.3, CC6.4, C6.6, CC6.7, CC6.8, CC7.1, CC7.2, CC7.4, CC7.5, CC8.1, A1.1, A1.2
21 CFR 11.10(e)	7.1- secured and accessible 9-Audit Trails 10-Change and Configuration Management 12.4- data management/operators entries 14(c)-Electronic Signature	211.68	820.30(i) 820.70(i) 820.40	CC3.1, CC5.2, CC5.3, CC6.1, CC6.6, CC6.7, CC6.8, CC7.1, CC7.2, CC7.3, CC8.1
21 CFR 11.10(f)	5-Data, 6- Accuracy Checks	211.68(b) 211.194(d) 211.68(c)	820.25 820.70(a) 820.180 820.184	Not Covered