8. ASSESS HOW WELL YOU CONFORM TO ISO'S REMEDIAL REQUIREMENTS

8.1 PLANNING REQUIREMENTS

1	Do you plan monitoring, measurement, and analytical processes?		
2	Do you plan how monitoring will be used to ensure conformity and effectiveness?		
3	Do you plan how it will be used to ensure that requirements are being met?		
4	Do you plan how it will be used to ensure products meet requirements?		
5	Do you plan how it will be used to ensure QMS meets requirements?		
6	Do you plan how it will be used to maintain the effectiveness of your QMS?		
7	Do you plan how measurement will be used to ensure conformity and effectiveness?		
8	Do you plan how it will be used to ensure that requirements are being met?		
9	Do you plan how it will be used to ensure that products meet requirements?		
10	Do you plan how measurement will be used to ensure product conformance?		
11	Do you plan how statistical measurement techniques will be used?		
12	Do you plan how it will be used to ensure that QMS meets requirements?		
13	Do you plan how measurement will be used to ensure QMS conformance?		
14	Do you plan how statistical measurements will be used to study QMS?		
15	Do you plan how it will be used to maintain the effectiveness of your QMS?		
16	Do you plan how statistical measurements will be used to maintain QMS?		
17	Do you plan how analytics will be used to ensure conformity and effectiveness?		
18	Do you plan how analytics will be used to ensure that requirements are met?		
19	Do you plan how they will be used to ensure that products meet requirements?		
20	Do you plan how analytics will be used to ensure product conformance?		

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21	Do you plan how analytical statistical techniques will be used?		
22	Do you plan how analytics will be used to ensure QMS meets requirements?		
23	Do you plan how analytics will be used to ensure QMS conformance?		
24	Do you plan how analytical statistics will be used to study QMS?		
25	Do you plan how analytics will be used to maintain the effectiveness of QMS?		
26	Do you plan how analytical statistical methods will be used to maintain QMS?		
27	Do you use monitoring, measurement, and analytical processes?		
28	Do you apply your organization's monitoring methods?		
29	Do you monitor your organization's conformance?		
30	Do you monitor product conformance?		
31	Do you monitor QMS conformance?		
32	Do you monitor the effectiveness of your QMS?		
33	Do you apply your organization's measurement methods?		
34	Do you measure your organization's conformance?		
35	Do you measure product conformance?		
36	Do you measure QMS conformance?		
37	Do you measure the effectiveness of your QMS?		
38	Do you apply your organization's analytical methods?		
39	Do you analyze your organization's conformance?		
40	Do you analyze product conformance?		
41	Do you analyze QMS conformance?		
42	Do you analyze the effectiveness of your QMS?		

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8.2 RESEARCH REQUIREMENTS

8.2.1 IMPLEMENT SUITABLE FEEDBACK METHODS AND PROCEDURES

43	Have you established feedback methods and procedures?		
44	Did you establish customer feedback methods and procedures?		
45	Did you establish production feedback methods and procedures?		
46	Did you establish post-production feedback methods and procedures?		
47	Did you document your feedback methods and procedures?		
48	Did you implement your feedback methods and procedures?		
49	Do you gather information about your customers?		
50	Do you monitor customer perception and satisfaction?		
51	Do you find out if customer requirements are being met?		
52	Do you gather information about your production activities?		
53	Do you gather information about your post-production activities?		
54	Do you review your experience if regulations expect you to do so?		
55	Do you maintain your feedback methods and procedures?		
56	Do you examine the information you have gathered?		
57	Do you use your feedback to measure QMS effectiveness?		
58	Do you use your feedback to facilitate risk management?		
59	Do you use it to monitor and maintain product requirements?		
60	Do you use your feedback to support improvement processes?		

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61	Do you use your feedback to enhance product realization?		
8.2.2 DEVELOP AND DOCUMENT COMPLAINT HANDLING PROCEDURES			
62	Have you established complaint handling procedures?		
63	Do you expect procedures to comply with relevant regulations?		
64	Do you expect complaints to be handled in a timely manner?		
65	Do you expect uninvestigated complaints to be documented?		
66	Do you expect people to justify why each complaint is ignored?		
67	Do you document your complaint handling procedures?		
68	Do you specify related responsibilities and requirements?		
69	Do you specify how feedback should be managed?		
70	Do you specify how feedback should be received?		
71	Do you specify how feedback should be recorded?		
72	Do you specify how feedback should be evaluated?		
73	Do you explain when feedback is treated as a complaint?		
74	Do you specify how complaints should be investigated?		
75	Do you specify how complaints are discussed with external parties?		
76	Do you explain when information may be exchanged with others?		
77	Do you specify how information should be reported?		
78	Do you specify when reports are sent to regulatory authorities?		
79	Do you specify how remedial action should be initiated?		
80	Do you specify when corrections need to be initiated?		
81	Do you specify when corrective actions need to be initiated?		

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82	Do you specify how related products should be handled?		
83	Do you specify how related records should be maintained?		
84	Do you specify how complaints should be documented?		
85	Do you explain how to document uninvestigated complaints?		
86	Do you specify how remedial actions should be documented?		
87	Do you explain how corrections should be documented?		
88	Do you explain how corrective actions should be documented?		
89	Did you implement your complaint handling procedures?		
90	Do you maintain your complaint handling procedures?		
8.2.3 ESTABLISH AND MAINTAIN REGULATORY REPORTING PROCEDURES			
91	Do you establish reporting procedures when regulators expect you to report to them?		
92	Do you create procedures if they expect you to notify them about adverse events?		
93	Do you create procedures if they expect you to notify them about advisory notices?		
94	Do you document reporting procedures if regulators expect you to report to them?		
95	Do you implement reporting procedures if regulators expect you to report to them?		
96	Do you notify regulators when complaints meet adverse event reporting criteria?		
97	Do you notify regulators when your organization issues official advisory notices?		
98	Do you maintain reporting procedures if regulators expect you to report to them?		
99	Do you keep a record of your organization's regulatory reports and notifications?		
8.2.4 PLAN AND PERFORM INTERNAL AUDITS AT PLANNED INTERVALS			
100	Have you established an internal audit procedure?		
101	Did you document your internal audit procedure?		

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8. ASSESS HOW WELL YOU CONFORM TO ISO'S REMEDIAL REQUIREMENTS

102	Do you specify how internal audits should be planned?		
103	Do you define internal audit planning responsibilities?		
104	Do you define internal audit planning requirements?		
105	Do you specify how internal audits should be performed?		
106	Do you define internal audit performance responsibilities?		
107	Do you define internal audit performance requirements?		
108	Do you specify how internal audit records should be kept?		
109	Do you define internal audit record keeping responsibilities?		
110	Do you define internal audit record keeping requirements?		
111	Do you specify how internal audit results should be reported?		
112	Do you define internal audit reporting responsibilities?		
113	Do you define internal audit reporting requirements?		
114	Did you implement your organization's internal audit procedure?		
115	Do you maintain your organization's internal audit procedure?		
116	Do you plan your organization's internal audit program?		
117	Do you use your audit procedure to plan your audits?		
118	Do you clarify the scope of your internal audits?		
119	Do you establish your internal audit criteria?		
120	Do you examine the results of previous audits?		
121	Do you define and record your audit methods?		
122	Do you consider the status and importance of audit areas?		
123	Do you give more attention to important audit areas?		
124	Do you give more attention to important processes?		

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AB. OUR ISO 13485 CONFORMANCE AUDIT QUESTIONNAIRES

8. ASSESS HOW WELL YOU CONFORM TO ISO'S REMEDIAL REQUIREMENTS

125	Do you select impartial and objective auditors?		
126	Do you make sure they don't audit their own work?		
127	Do you specify how often audits should be performed?		
128	Do you schedule internal audits at planned intervals?		
129	Do you carry out your internal audits at planned intervals?		
130	Do you determine if your organization's QMS meets requirements?		
131	Do you find out whether QMS meets ISO 13485 2016 requirements?		
132	Do you find out whether QMS meets your organization's own requirements?		
133	Do you find out whether QMS meets the requirements imposed by regulators?		
134	Do you determine if your QMS conforms to planned arrangements?		
135	Do you find out whether your QMS conforms to documented arrangements?		
136	Do you determine if your organization's QMS is effectively implemented?		
137	Do you determine if your QMS is being maintained effectively?		
138	Do you maintain a record of audit plans and performance?		
139	Do you establish a record of your planned audit program?		
140	Do you establish a record of your audit scopes and activities?		
141	Do you identify the areas and processes being audited?		
142	Do you document your audit conclusions and results?		
143	Do you eliminate all detected nonconformities and causes?		
144	Do you make corrections and take corrective action without undue delay?		
145	Do you expect managers to act whenever problems are found in their areas?		
146	Do you follow-up on steps taken to resolve nonconformities?		
147	Do you verify the corrections and the corrective actions that are taken?		

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148	Do you report corrections, corrective actions, and verification results?		
8.2.5 FIND OUT WHETHER PROCESSES ACHIEVE PLANNED RESULTS			
149	Do you establish suitable methods to monitor and measure each QMS process?		
150	Do you develop methods that can find out if planned results are being achieved?		
151	Do you apply suitable methods to monitor and measure each QMS process?		
152	Do you determine whether or not each QMS process is achieving planned results?		
153	Do you monitor each QMS process to see if planned results are being achieved?		
154	Do you measure each QMS process to see if planned results are being achieved?		
155	Do you take remedial action whenever processes fail to achieve planned results?		
156	Do you make corrections whenever a process fails to achieve planned results?		
157	Do you take corrective action whenever a process fails to achieve planned results?		
8.2.6 MONITOR AND MEASURE MEDICAL DEVICE CHARACTERISTICS			
158	Do you monitor and measure your organization's product characteristics?		
159	Do you verify that relevant medical device requirements are being met?		
160	Do you verify products at applicable stages during product realization?		
161	Do you verify products in accordance with planned arrangements?		
162	Do you verify products in accordance with documented arrangements?		
163	Etcetera ...		

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