## 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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| 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

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| 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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