# Annex C: Surveillance Plan

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| **Surveillance Plan ISO 13485:2016** | | | | | |
| **1**: Initial Audit  **2:** Surveillance 1 Audit  **3**: Surveillance 2 Audit  **4**: Recertification Audit | | **Plan** | | | |
| **1**  **(202X)** | **2**  **(202X)** | **3**  **(202X)** | **4**  **(202X)** |
| **4 Quality management system** | | | | | |
| **4.1** | General requirements |  |  |  |  |
| **4.2** | Documentation requirements |  |  |  |  |
| **5 Management responsibility** | | | | | |
| **5.1** | Management commitment |  |  |  |  |
| **5.2** | Customer focus |  |  |  |  |
| **5.3** | Quality policy |  |  |  |  |
| **5.4** | Planning |  |  |  |  |
| **5.5** | Responsibility, authority and communication |  |  |  |  |
| **5.6** | Management review |  |  |  |  |
| **6 Resource management** | | | | | |
| **6.1** | Provision of resources |  |  |  |  |
| **6.2** | Human resources |  |  |  |  |
| **6.3** | Infrastructure |  |  |  |  |
| **7 Product realization** | | | | | |
| **7.1** | Planning of product realization |  |  |  |  |
| **7.2** | Customer-related processes |  |  |  |  |
| **7.3** | Design and development |  |  |  |  |
| **7.4** | Purchasing |  |  |  |  |
| **7.5** | Production and service provision |  |  |  |  |
| **7.6** | Control of monitoring and measuring equipment |  |  |  |  |
| **8 Measurement, analysis and improvement** | | | | | |
| **8.1** | General |  |  |  |  |
| **8.2** | Monitoring and measurement |  |  |  |  |
| **8.3** | Control of nonconforming product |  |  |  |  |
| **8.4** | Analysis of data |  |  |  |  |
| **8.5** | Improvement |  |  |  |  |
| **Additional requirements** | | | | | |
|  | Use of logo and trademark |  |  |  |  |
|  | Verification of Adverse events, advisory notices and recalls |  |  |  |  |
|  | Documentation and processes defined in the management system developed by the client |  |  |  |  |

*For completed visits, mark “X” in the box for each clause/process covered.*

*For planned visits mark “O” in the box for each clause/process to be covered*