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| POLICY GAP ANALYSIS | | | | | | |  | | |
|  | **Policy: ISO 13485:2016 - Medical devices**  Responsible: John Doe  Date: 01-05-2021 | | | | |  |
|  |  |  |  |  |  |  |  |  |  |
|  | POLICY AREA | | Clear About Requirement | Current Requirement Coverage | Gap Description | Action required | Person Responsible | Due Date |  |
|  | **SECURITY POLICY** | | | | | | | |  |
|  | 3.1. | Information security | YES | POOR | Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas porttitor congue massa. | Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. | Outsourcing | 05/12/2021 |  |
|  | 3.4. | Review and evaluation | NO | NONE | Vivamus a tellus. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Proin pharetra nonummy pede. | Mauris et orci. Aenean nec lorem. In porttitor. Donec laoreet nonummy augue. | M.Petters | 06/23/2021 |  |
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|  | **ASSET CLASIFICATION AND CONTROL** | | | | | | | |  |
|  | 5.1. | Inventory of assets | YES | POOR | Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas porttitor congue massa. | Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. | W. Bradley | 05/12/2021 |  |
|  | 5.2. | Information of labeling | YES | POOR | Vivamus a tellus. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Proin pharetra nonummy pede. | Mauris et orci. Aenean nec lorem. In porttitor. Donec laoreet nonummy augue. | C. Williams | 06/11/2021 |  |
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|  | **PHYSICAL AND ENVIRONMENTAL SECURITY** | | | | | | | |  |
|  | 8.1. | Physical security perimeter | YES | POOR | Suspendisse dui purus, scelerisque at, vulputate vitae, pretium mattis, nunc. Mauris eget neque at sem venenatis eleifend. Ut nonummy. | Fusce aliquet pede non pede. Suspendisse dapibus lorem pellentesque magna. Integer nulla. Donec blandit feugiat ligula. | Outsourcing | 05/20/2021 |  |
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|  | **COMMUNICATIONS AND OPERATIONS MANAGEMENT** | | | | | | | |  |
|  | 10.1. | Incident management procedures | YES | NONE | Donec hendrerit, felis et imperdiet euismod, purus ipsum pretium metus, in lacinia nulla nisl eget sapien. | Donec ut est in lectus consequat consequat. Etiam eget dui. Aliquam erat volutpat. | B.Bill | 05/28/2021 |  |
|  | 10.5. | External facilities management | YES | NONE | Suspendisse dui purus, scelerisque at, vulputate vitae, pretium mattis, nunc. Mauris eget neque at sem venenatis eleifend. Ut nonummy. | Fusce aliquet pede non pede. Suspendisse dapibus lorem pellentesque magna. Integer nulla. Donec blandit feugiat ligula. | Outsourcing | 05/30/2021 |  |
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