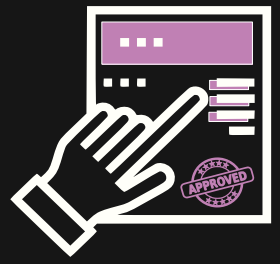
POLICY GAP ANALYSIS



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
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
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
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