

TGA Reclassification Readiness Checklist

- **Confirm if your device is affected by changes to classification made in 2024.**
- **Verify updated GMDN codes and intended use.**
- **Identify the new device classification under revised TGA rules.**
- **Update the Technical Dossier as needed.**
- **Update your QMS to reflect new classification requirements.**
- **Check if additional conformity assessment is needed.**
- **Prepare updated labeling, IFU, and marketing materials.**
- **Ensure sponsor details and ARTG entries are accurate.**
- **Submit required applications before the deadline.**
- **Maintain documentation for audit and post-market review.**