























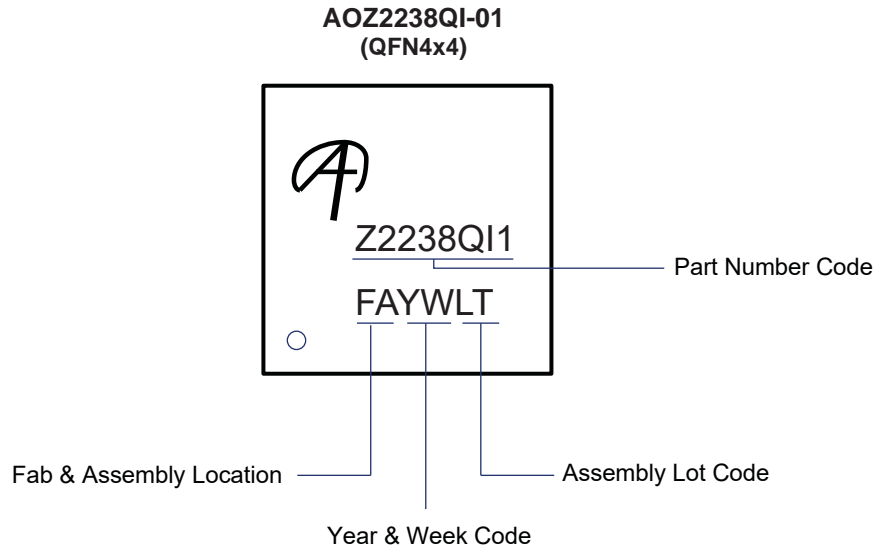








**Part Marking**



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As used herein:

- |   |   |
|---|---|
| <p>1. Life support devices or systems are devices or systems which, (a) are intended for surgical implant into the body or (b) support or sustain life, and (c) whose failure to perform when properly used in accordance with instructions for use provided in the labeling, can be reasonably expected to result in a significant injury of the user.</p> | <p>2. A critical component in any component of a life support, device, or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.</p> |
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