Patient Guard
Medical Device Quality & Regulatory Assurance

UK Medical Device Classification Checklist

- [ ] Define the intended purpose clearly using UK MDR-compliant language.
- [ ] Verify the device's mode of action to ensure it falls within the medical device scope.
- [ ] Identify invasiveness and duration of bodily contact.
- [ ] Assess whether the device is active or contains software.
- [ ] Review UK MDR classification rules (Annex IX MDD 93/42/EEC).
- [ ] Check MHRA borderline guidance for borderline or cosmetic products.
- [ ] Determine device class (I, Is, Im, Ir, IIa, IIb, III).
- [ ] Evaluate the classification impact on UKCA marking and conformity assessment.
- [ ] Confirm whether Approved Body involvement is required.
- [ ] Document classification rationale in technical documentation.
- [ ] Review whether accessories require independent classification.
- [ ] Reassess classification after any software or design updates.

Regulatory & Quality Specialists

Speak to an expert

Contact us today for more information

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