Intended Purpose Checklist

Topic	Check
Meta-Information	
Product identification	
Adherence and limitations of the document	
Instructions for using the template	
Summary	
Concise summary of the intended use	
Medical Purpose	
Medical purpose (diagnosis, treatment, monitoring, etc.)	
Other intended uses	
User Groups	
Educational level or training required	
Typical user tasks	
Language and cognitive capabilities	
Special equipment (e.g., gloves, protective gear)	
Patients	
Conditions treated or monitored	
Body parts affected	
Contraindications	
Demographics (age, sex, etc.)	
Context of Use	
Physical environment (light, temperature, noise, vibrations, etc.)	
Social environment (stress, shift work, distractions, etc.)	
Power supply (voltage, frequency, plugs etc.)	
Portability (handheld, fixed)	
Exclusions	
Uses not intended for the device	
Other	
Hardware/software requirements	
Networking, firewalls, and hazards analysis	