Innovation and Safety for Wearable Technology

Wearable technology occupies a prominent place in our everyday lives. These products incorporate miniaturized Internet of Things (IoT) sensors/devices with corresponding software to detect and process body signals and data to transmit, analyze and interpret information. Usually worn close to the skin and in clothing, wearables are used for entertainment, navigation, healthcare monitoring and wellness.

For wearables, areas of risk include:
- Product safety and performance
- Battery safety
- Data security
- Toxicology
- Interoperability
- Human factors/usability

Wearables performance expectations

Users of wearable products have expectations for the performance of their devices. To meet these expectations and properly get these products to market, wearable manufacturers and developers must consider:
- 5G connectivity
- Product performance and reliability
- Regulatory and compliance requirements

Mitigating those risks early in development helps create consumer satisfaction, lending itself to device safety, reliability and increased speed to market.

Wearables safety and compliance testing

Wearable technologies may require safety certification and regulatory testing to achieve market access or regulatory clearance. Our experts can guide you through the current regulatory requirements and available testing for your wearable device with testing for:

- Electrical safety
- Battery safety
- Electrical and motor systems
- SAR testing
- Toxicology
- Cybersecurity
- Electromagnetic compatibility (EMC)
- Wireless Device Testing and Certification Solutions
- Certification
- Interoperability
- Usability
- Smart clothing and footwear quality and performance testing, and claims verification
- Custom testing and execution of verification and validation protocols

Wearable technology standards

The safety and performance of the device in conjunction with other devices are crucial to consider, as some medical devices such as defibrillators and electro-surgical instruments necessarily emit high levels of EM radiation to perform their functions. The FDA and Health Canada use the IEC versions of these standards to meet their requirements. In the U.S., devices used in hospitals should meet the Occupational Safety and Health Administration (OSHA) requirements, and they should also be certified by a Nationally Recognized Test Laboratory (NRTL).

Standards to be tested against include:

Wellness or nonmedical wearable	IEC/UL 62368-1 Audio/Visual, Information and Communication Technology Equipment — Part 1: Safety Requirements
Medical device safety	IEC 60601-1, IEC 60601-1-11 — and all related standards
EMC	IEC 60601-1-2 (or equivalent for nonmedical applications)
Usability	IEC 60601-1-6 (or equivalent for nonmedical applications)
Biocompatibility	ISO 10993
Software cybersecurity	ANSI/CAN/UL 2900 Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements
Software Lifecycle Process	IEC 62304
SAR for wireless communication devices in EU	EN 50566: 2013, EN 50566: 2013/AC:2014, EN 50360: 2001, EN 62209-1: 2006, EN 62209-2: 2010, EN 62311: 2008
AR/VR/MR equipment	ANSI/CAN/UL 8400 Standard for Safety for Virtual Reality, Augmented Reality and Mixed Reality Technology Equipment — Part 1: Safety (in development, world's first dedicated equipment safety standard for AR/VR/MR)

UL can help you achieve compliance and speed to market with end-to-end testing and certification solutions for your wearable products. Contact us today.

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