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:

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<tr>
<th>Category</th>
<th>Standards</th>
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<tr>
<td>Wellness or nonmedical wearable</td>
<td>IEC/UL 62368-1 Audio/Visual, Information and Communication Technology Equipment – Part 1: Safety Requirements</td>
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<td>Medical device safety</td>
<td>IEC 60601-1, IEC 60601-1-11 – and all related standards</td>
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<td>EMC</td>
<td>IEC 60601-1-2 (or equivalent for nonmedical applications)</td>
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<td>Usability</td>
<td>IEC 60601-1-6 (or equivalent for nonmedical applications)</td>
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<td>Biocompatibility</td>
<td>ISO 10993</td>
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<td>Software Lifecycle Process</td>
<td>IEC 62304</td>
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