Regulation Requirement for Wearable Electronic Products

Specific Requirement on Safety, EMC, Chemical, Battery and Energy Saving

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What are wearable technologies?

Wearable technology, wearables, fashionable technology, wearable devices, tech togs, or fashion electronics are clothing and accessories incorporating computer and advanced electronic technologies. The designs often incorporate practical functions and features, but may also have a purely critical or aesthetic agenda.

*Wikipedia*
Wearable Technologies Product Segmentation

- Infotainment
- Fitness & Wellness
- Healthcare & Medical
- Industrial & Military
Wearable Tech – Fashion of the Future

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Google Glass
No word of a UV-rated pair yet, but apparently there will be a version that can attach to your own varifocals.
Try this: www.google.com/glass/start/

LED Headwear
Created using a 3D printer, this 2016-style headwear is covered in LEDs that respond to head movement.
Try this: absurddeee.com/go!

RFID Wristband
With supporting software, this wristband that uses RFID technology, can work as a paperless ticket, cashless wallet and a contactless way of updating Facebook.
Try this: www.lidcband.co.uk

Glove Tricorder
Figure out exactly how drunk you are with this self-diagnosing sensory glove from Med Sensation. Sadly, it won’t cure that hangover though.
Try this: http://medsensation.com

Flexible Display Map
Most of the tech giants are on the verge of launching some form of flexible display. How about using one for a festival schedule that you could also use to watch video clips of the acts you missed.
Try this: http://engt.co/laxTsz

Sensor Socks
These socks have embedded sensors within the fabric that and can notify you of your balance via a mobile. We can’t guarantee they won’t smell though.
Try this: www.hauspsylos.com

Source: Crunchwear.com
## Key Challenge for Wearable Industry

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<td>Bio-compatibility (for medical devices)</td>
<td>Implants existing in harmony with the tissue</td>
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Applicable safety testing standards including

- IEC 60950-1
- IEC 60065
- IEC 62368
- IEC 60601-1
- Others (Based on the intended functions)
Safety Requirement

Minimum markings requirements:

• Manufacturer’s name or trade-mark or identification mark;

• Manufacturer’s model identification or type reference;

• Other certification marks (NRTL, CE, TUV…………).
Thermal requirements:

- Materials used in components and in the construction of the equipment shall be selected as that under normal operation, temperatures do not exceed safe values.

- E.g.: The temperatures of accessible parts in operator access areas shall not exceed the values requested by standard.
Physical requirements-Mechanical hazard:

- Under conditions of normal use, units and equipment shall not become physically unstable to the degree that they could become a hazard to an operator or to a service person.

- E.g.: Clamp, Sharp edges and corners.
Batteries testing:

Equipment containing batteries shall be designed to reduce the risk of fire, explosion and chemical leaks under normal conditions and after a single fault in the equipment.

- Portable secondary sealed cells and batteries (other than button) containing alkaline or other non-acid electrolyte shall comply with IEC 62133.
- Overcharging of a rechargeable battery.
- Unintentional charging of a non-rechargeable battery.
- Reverse charging of a rechargeable battery.
- Excessive discharging rate for any battery.
Safety Requirement

Headphone test (sound pressure):

Protection against excessive sound pressure from personal music players that are closely coupled to the ear. It also specifies requirements for earphones and headphones intended for use with personal music players.
IP Testing - degrees of protection provided by enclosure

For example: IP 54..............................

- The first digit (5) denote: Degrees of protection against solid foreign objects.
- The second digit (4) denote: Degrees of protection against ingress of water.
Safety Requirement

Hazardous radiations-Light emitting diodes (LEDs)

Equipment containing LEDs that produce optical radiation in excess of the limits specified in IEC 62471 in the wavelength range 200 nm to 3000 nm, as specified by the lamp manufacturer, shall be provided with means to reduce the likelihood of optical radiation exceeding the limits specified in IEC 62471 from appearing in user accessible areas.

Low power applications of LEDs need not comply with IEC 62471.
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CE-R&TTE Requirements:
Most of the wearable device adopts wireless radio techniques, so R&TTE directive need to be met, applicative standards as below:

Radio standards:
• EN 301 908-1 V6.2.1 (3G, 4G)
• EN 301 511 V9.0.2 (2G)
• EN 300 328 V1.8.1 (2.4GHZ WIFI, Bluetooth)
• EN 301 893 V1.7.1 (5GHz WIFI)
• EN 300440-2 V1.4.1(GPS)
• EN 302 291-2 V1.1.1 (13.56MHz NFC)

EMC standard:
• EN 301 489-1 V 1.9.2 (Common technical requirements)
• EN 301 489-24 V1.5.1 (3G, 4G)
• EN 301 489-7 V1.3.1 (2G)
• EN 301 489-17 V2.2.1 (2.4GHz/5GHz WIFI, Bluetooth)
• EN 301 489-3 V1.6.1 (GPS, NFC)

Safety and Health standard:
• EN 60950-1
• EN 60065
• EN 62479:2010 (Output power < 20mW)
• EN 50364: 2010 (NFC SAR evaluation)
• EN 62311:2008 (Output power > 20mW)
• EN 62209-1: 2006 (Head SAR)
• EN 62209-2: 2010 (Body SAR)
• EN 50566: 2013 (Body SAR)
**CE-EMC Requirements:**

If the wearable device has some wired function (e.g. charging, audio) CE-EMC directive also need to be met.

**EMC standards:**

- EN 55022: 2010 (Emission for IT device)
- EN 55024: 2010 (Immunity for IT device)
- EN 55013: 2013 (Emission for AV device)
- EN 61000-3-2:2014 (Harmonic)
- EN 61000-3-3:2013 (Flicker)
- ........
FCC Requirements:
the applicative standards and regulations for wireless part as below:

Radio standards:
• Part 22, 24, 27 (2G, 3G, 4G)
• Part 15 C (2.4G WIFI, Bluetooth, NFC)
• Part 15 E (5G WIFI)

Knowledge Data Base Policies for SAR
• OET Bulletin 65
• FCC 47CFR § 2.1093 [Portable devices]
• KDB 248227 (D01 802.11 a/b/g Transmitters)
• KDB 447498 (D01 Mobile and Portable Procedures and EA Polices)
• ......

EMC standard:
If the wearable device has some wired function (e.g. charging, audio)
• Part 15 B
IC Requirements:
the applicative standards and regulations for wireless part as below:

Radio standards:
• RSS-132, RSS-133, RSS-139, RSS-130 (2G, 3G, 4G)
• RSS-210 (2.4G WIFI, Bluetooth, NFC)

RF/SAR for Portable covered in
• RSS-102

EMC standard:
If the wearable device has some wired function (e.g. charging)
• ICES-003
Overview

1. Safety Requirement
2. EMC Requirement
3. Chemical Requirement
4. Battery Requirement
5. Energy Saving Requirement
6. Question and Answer
Chemical Concern – What’s the “Health Hazard” brought about by Hazardous Substances???

- Risk of allergenic reaction
- Risk of carcinogenicity and allergenic reaction
- Volatile, irritant and risk of carcinogenicity
- Endocrine disorders, developmental delays, damages to the reproductive system and infertility
- Damage the kidneys and the bones
- Damage the nervous system
Chemical Concern – How to find the Skin contact Hazardous Substances?

- **Heavy metals**
  - Nickel release
  - Hexavalent Chromium

- **Textile related substances**
  - Azo Dyes
  - Formaldehyde

- **Other Toxic organic substances**
  - PAHs (Polycyclic aromatic hydrocarbon):
  - Phthalates:
Chemical Concern – Another channel to damage our health - Circumstance

Persistent, Bio-accumulative and Toxic (PBT) or very Persistent and very Bio-accumulative (vPvB) Hazardous Substances will effect our health through Circumstance

We have below Regulation deal with them

- California Proposition 65
- REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)
- POPs (Persistent Organic Pollutants)
- WEEE (Waste Electrical and Electronic Equipment)
- RoHS (Restriction of the use of certain Hazardous Substances in electrical and electronic equipment)

RoHS Restricts substances
- 4 heavy metals (Cd, CrVI, Hg, Pb)
- 2 flame retardants (PBBs, PBDEs)
- 4 prior concern substances (DEHP, DBP, BBP, DIBP) in future
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Battery Requirement

Battery type and requirement for wearable product

Lithium ion cell
Lithium ion battery
Small Power bank

Global Standards:
- IEC 62133
- IEC 61960

EU Standards:
- EN 62133
- EN 61960

NA Standards:
- UL1642
- UL2054
Battery Requirement

Battery testing:
- Rated capacity
- Life cycle
- Over-charge/discharge
- External short circuit
- Thermal abuse
- Forced internal short-circuit
- Crush
- Vibration
- Low pressure
- Temperature cycling
- Mechanical shock
- Impact
- ...

Battery Test and certification Service:
- Safety
- Performance
- Transport Safety
- Global market access
- EMC
- Chemical
- Factory inspection service
- Customized
- ...

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Battery Requirement

Global Access

- TÜV SÜD
- IEC
- CB Scheme
- KCC
- PCT
- PSE
- BIS
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Energy Efficiency of Wearable Product

For Wearable Product, only the products with rechargeable battery need to consider the energy efficiency requirements. We only introduce mandatory requirement.

**Two types:**
1) charged by USB cable
2) charged by power supply

We need to consider energy saving requirements for **battery charger system** and **power supply**:

**Battery charger system** includes: USB connector/ Power supply + charging circuit + battery
Product charged by USB cable: following type 1 energy requirements need to be considered.

Battery charger system: California requires test and registration for CEC
The system included: USB connector + charging circuit + battery

Product charged by power supply: following type 7 energy requirements need to be considered.

1) Battery charger system:

   a: California requires test and registration for CEC

   b: Europe requires test for ErP

The system included: Power supply + charging circuit + battery
2) Power supply

a: United States requires test and registration for DOE

b: Europe requires test for ErP

c: Australia requires test and registration for MEPS

d: Canada requires test and registration for NrCAN

e: California requires test and registration for CEC

TÜV SÜD can provide the service for test and register for all of the above.
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