

# Regulation Requirement for Wearable Electronic Products

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

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Choose certainty.  
Add value.

# What are wearable technologies?

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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.

\*Wikipedi

# Wearable Technologies Product Segmentation



Infotainment



Fitness & Wellness

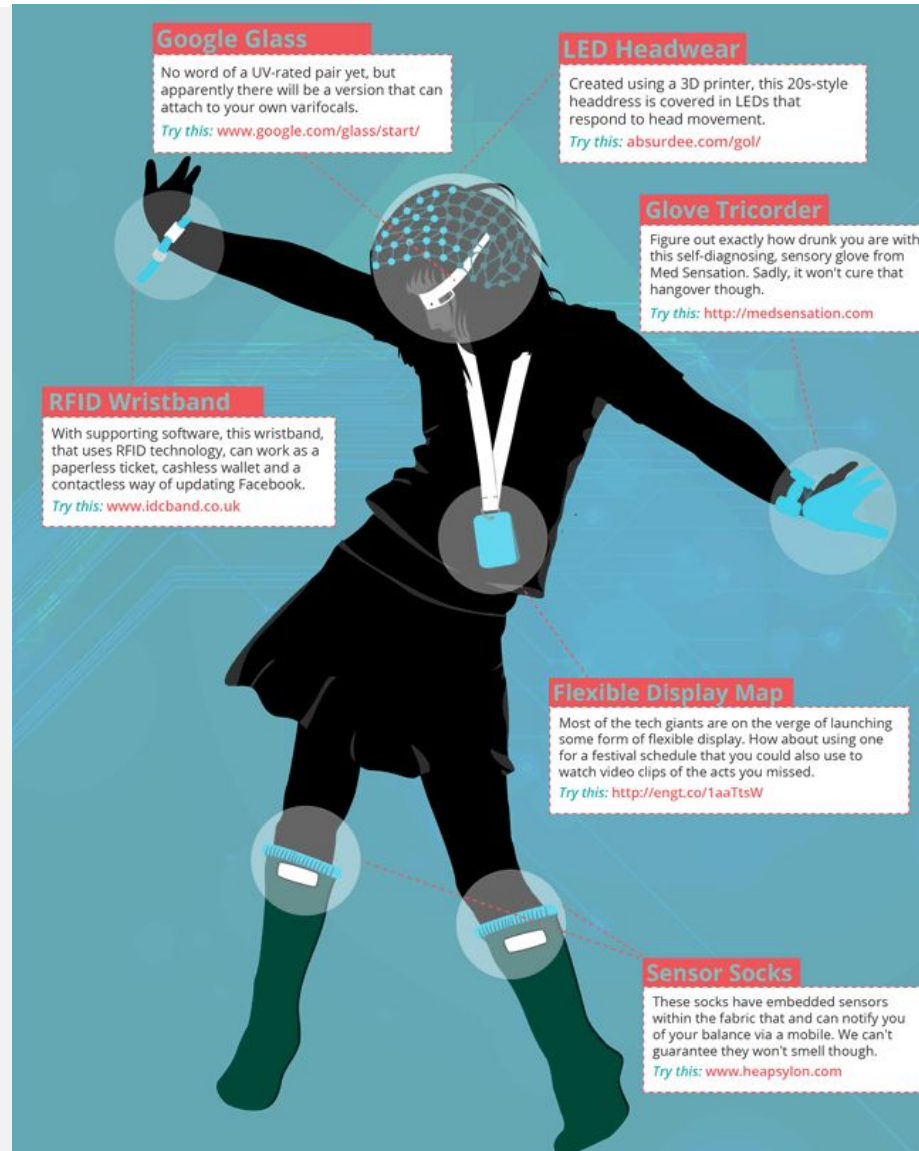


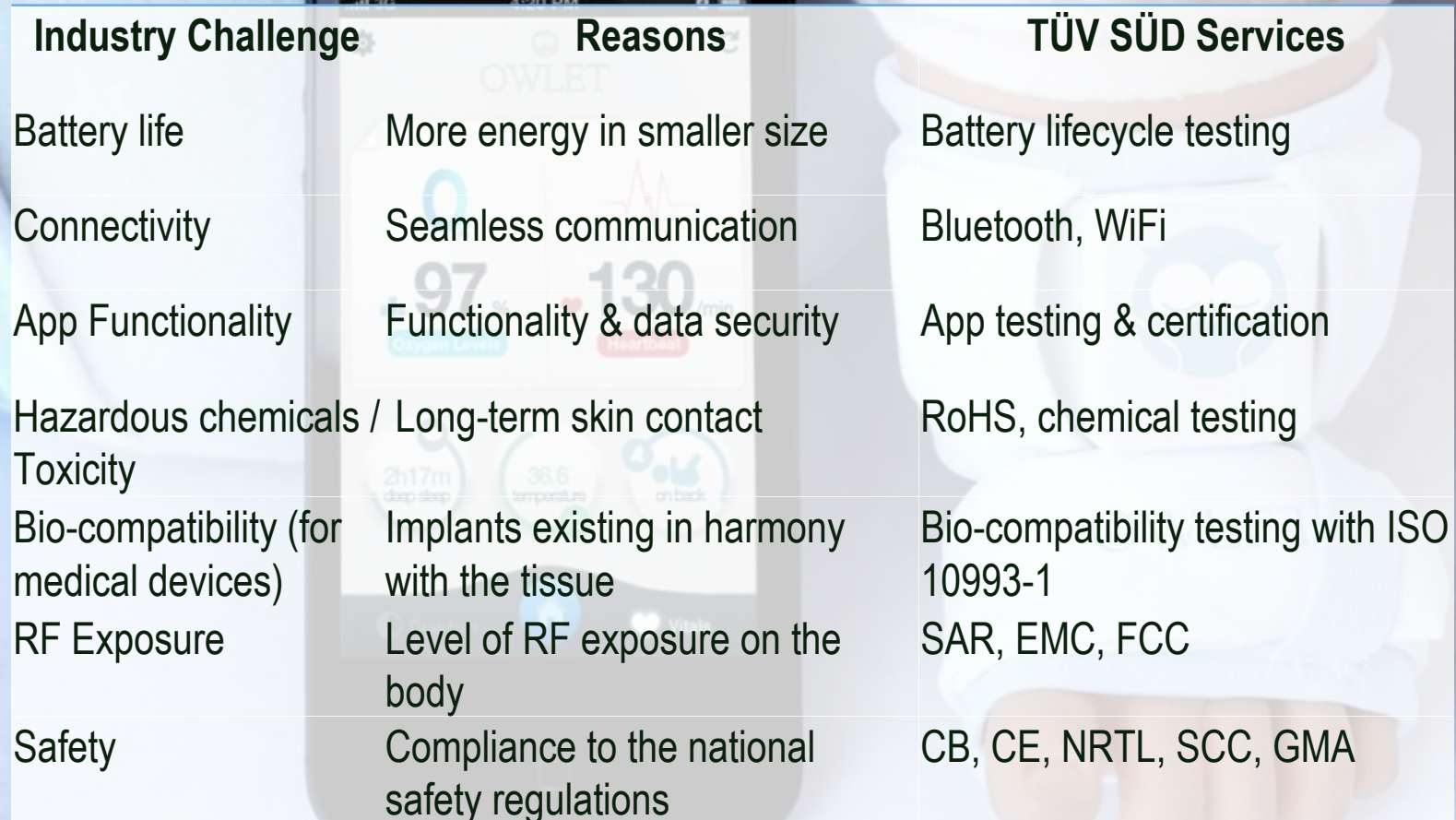
Healthcare & Medical



Industrial & Military







Industry Challenge	Reasons	TÜV SÜD Services
Battery life	More energy in smaller size	Battery lifecycle testing
Connectivity	Seamless communication	Bluetooth, WiFi
App Functionality	Functionality & data security	App testing & certification
Hazardous chemicals / Toxicity	Long-term skin contact	RoHS, chemical testing
Bio-compatibility (for medical devices)	Implants existing in harmony with the tissue	Bio-compatibility testing with ISO 10993-1
RF Exposure	Level of RF exposure on the body	SAR, EMC, FCC
Safety	Compliance to the national safety regulations	CB, CE, NRTL, SCC, GMA



## 1 Safety Requirement

2 EMC Requirement

3 Chemical Requirement

4 Battery Requirement

5 Energy Saving Requirement

6 Question and Answer

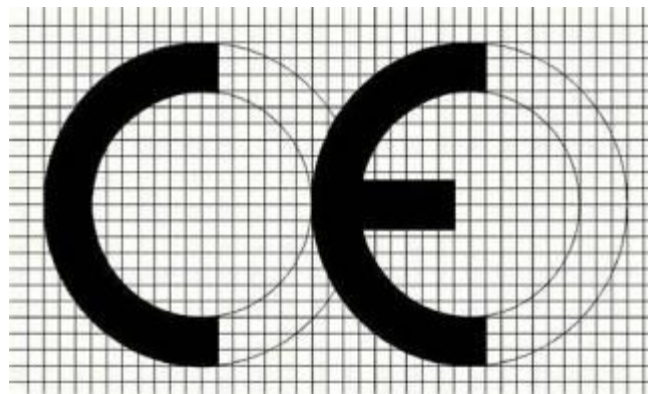
## Applicable safety testing standards including

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



## 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.



The product surface  
continuously  
touched by user

## Physical requirements-Mechanical hazard:

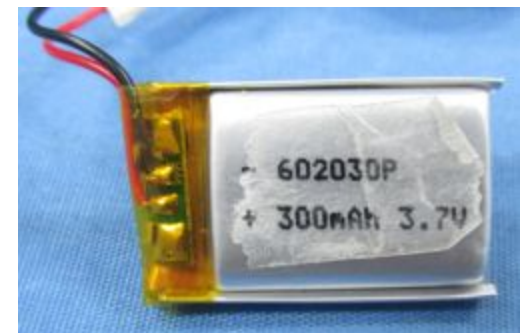
- Under conditions of normal use, units and equipment shall not become physically unstable to the degree that they could become a hazard to an operator or to a service person.
- E.g.: Clamp, Sharp edges and corners.



## Batteries testing:

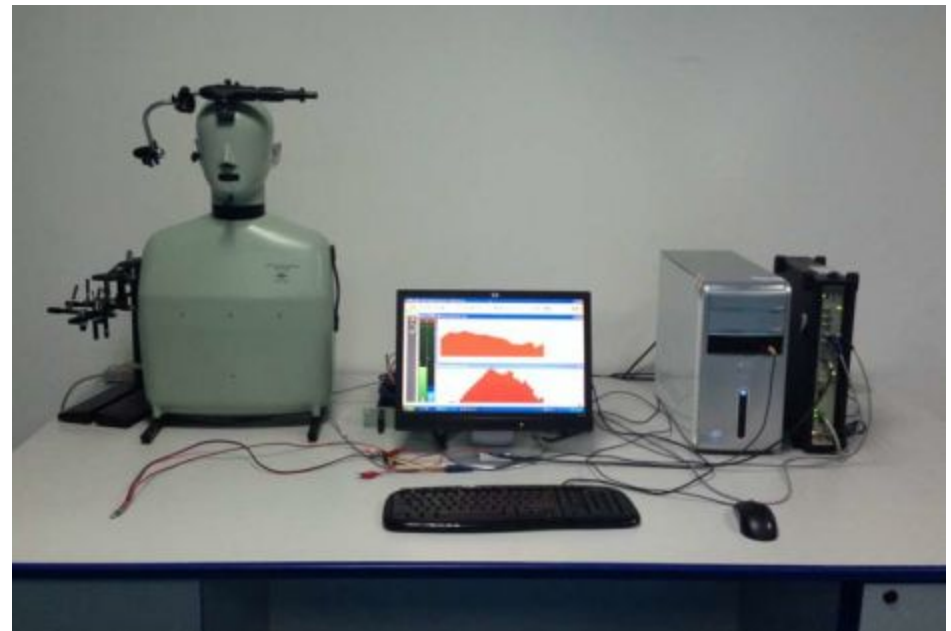
Equipment containing batteries shall be designed to reduce the risk of fire, explosion and chemical leaks under normal conditions and after a single fault in the equipment.

- 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.



## 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**.



## 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 ( Out put power < 20mW)
- EN 50364: 2010 ( NFC SAR evaluation)
- EN 62311:2008 ( Out put power > 20mW)
- EN 62209-1: 2006 (Head SAR)
- EN 62209-2: 2010 (Body SAR)
- EN 50566: 2013 (Body SAR)



# CE0168

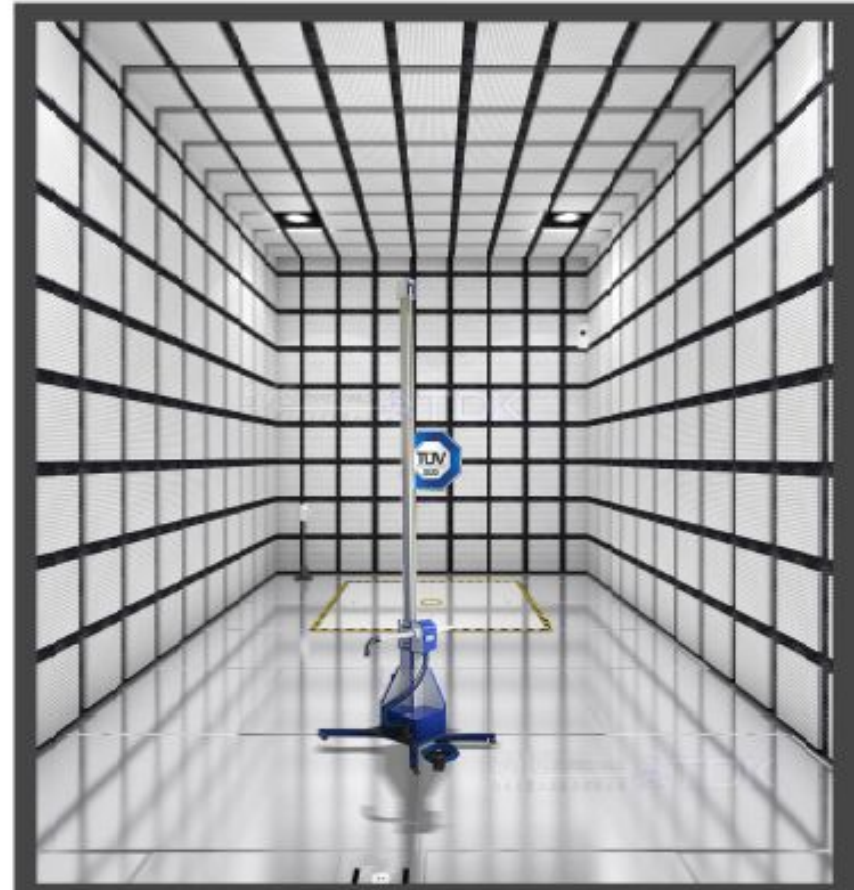


## CE-EMC Requirements:

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 55020:2007/A11:2011 (Immunity 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)

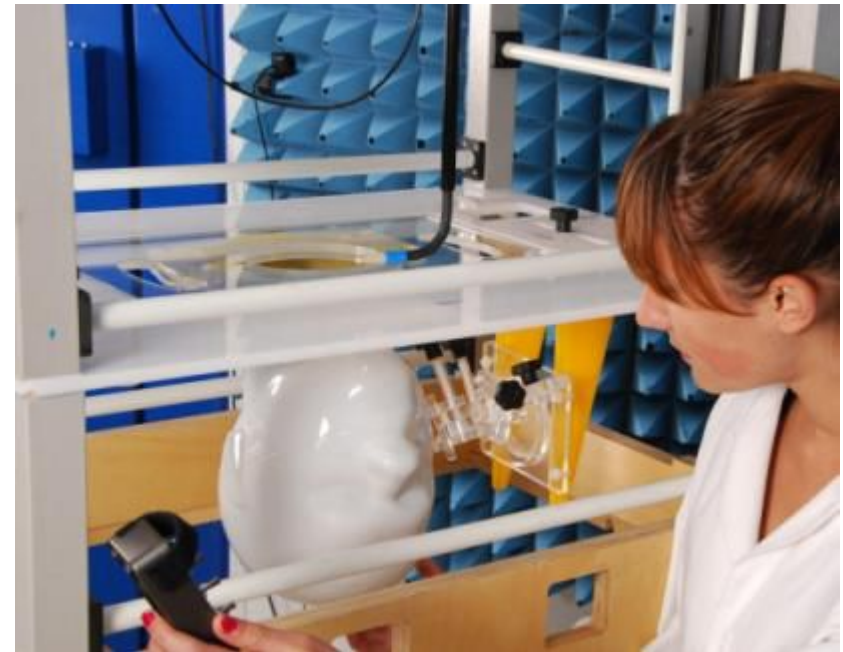
### Knowledge Data Base Policies for SAR

- 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 Policies)
- .....

### 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

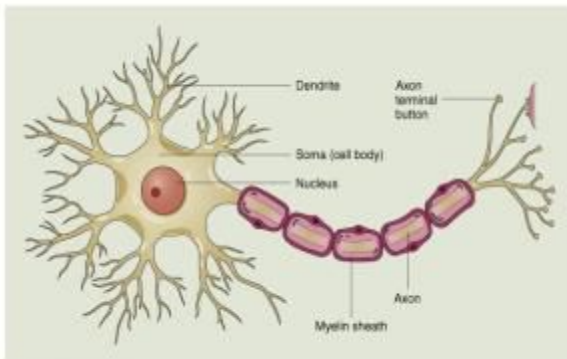


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# Chemical Concern – What’s the “Health Hazard” brought about by Hazardous Substances???



- 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 retardents (PBBs, PBDEs)
- ✓ 4 prior concern substances (DEHP, DBP, BBP, DIBP) in future





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## 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 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
- ...

# Battery Requirement



## Global Access



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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