



EAR ELECTRODE

FINISHED PRODUCT SPECIFICATION

Document No.: 【001GC-26030101】

Product Model: 【A09】

Effective Date: 【2026-06-01】

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Note:This specification applies to the A09 ear electrode finished product and covers its technical parameters, material requirements, test standards and acceptance criteria. It serves as the controlled reference for supplier production, mass-production inspection and customer qualification review and shall be strictly followed.

1 Basic Product Information

- Product Name: 【Ear Electrode】
- Product Model: 【A09】
- Material No.: 【FG-MED-00010】
- Product Category: 【Consumer Electronic Wellness Product】
- Intended Use: 【This ear electrode is an accessory for an ear relaxation massage device. It contacts the skin of the ear and transmits mild electrical signals to support comfort and relaxation. Its ergonomic profile conforms to the ear for comfortable wearing and stable conductivity. The product complies with applicable consumer electronic safety requirements and is not intended for medical use.】

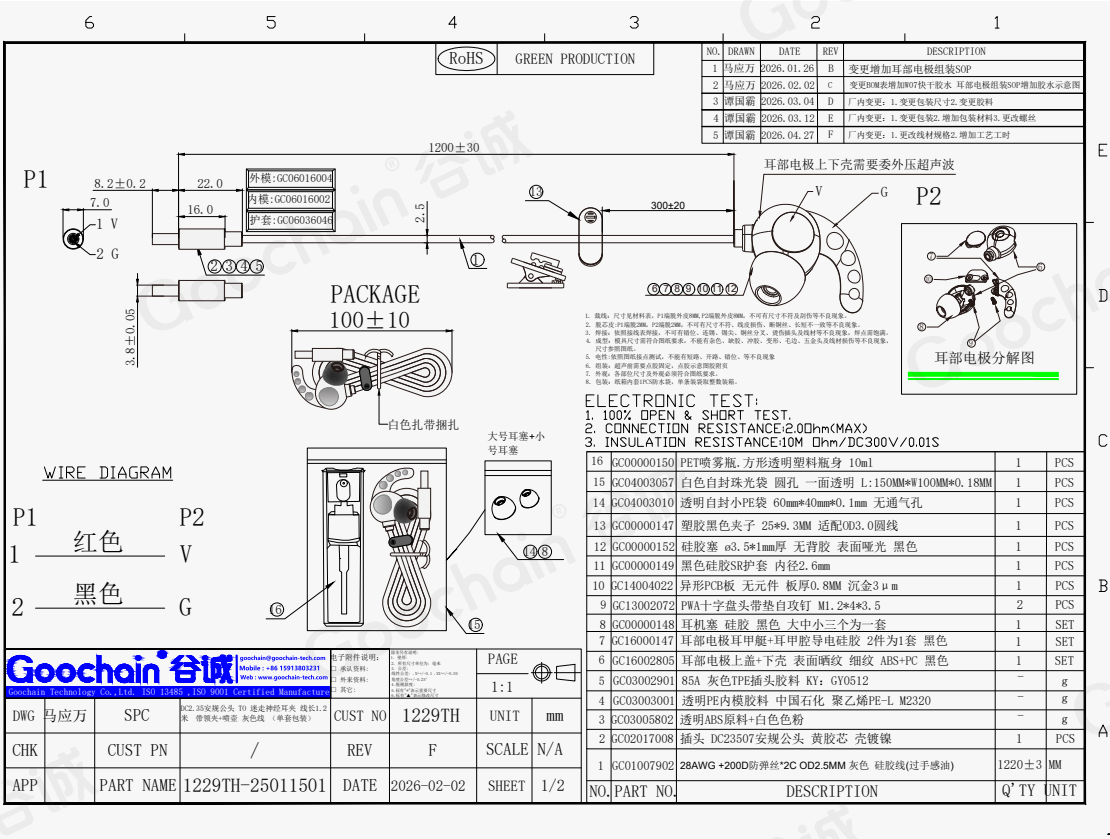
2 Appearance and Structure

2.1 Available Colors

- Matte White • Obsidian Black • Sea Salt Blue • Sakura Pink • Mint Green



2.2 Product Structure



3 Material Requirements and Environmental Compliance

3.1 Silicone Material

- Material:**Medical-grade conductive silicone, Shore A hardness 60 ± 5.
- Performance:**Odorless and non-irritating. The material complies with ISO 10993 biocompatibility requirements, with passing results for cytotoxicity, skin irritation and sensitization tests.
- Color:**Black. Other colors may be customized subject to prior commercial confirmation.
- Requirements:**The surface shall be smooth and free from burrs, bubbles and damage. The silicone shall fit securely against the internal PCB without any risk of detachment.

3.2 Conductive Layer Material

- Conductive Medium:**Carbon black is uniformly compounded into the silicone base to form an integral conductive region. The carbon black shall be evenly dispersed throughout the effective conductive area, with no material shortage or localized non-conductive gaps.
- Adhesion:**The conductive carbon black and silicone base shall be integrally bonded through vulcanization. No carbon shedding, particles or surface flaking is permitted after the adhesive-tape test.

3.3 PCB Material

- **Base Material and Thickness:**FR-4 epoxy-glass laminate, 1.0 ± 0.1 mm thick.
- **Surface Finish:** Immersion-gold finish, 2 μm thick. The surface shall be free from oxidation, exposed copper and scratches.
- **Soldering Workmanship:**The cable conductors shall be securely soldered to the PCB. Solder joints shall be full and free from cold soldering or false soldering. The conductors shall not detach when the cable is pulled.

3.4 Cable Material

- **Inner Conductor:** Multi-stranded oxygen-free copper conductor with good conductivity and no oxidation.
- **Outer Insulation:**Environmentally compliant PVC material, odorless, abrasion-resistant and pull-resistant. Insulation thickness: 0.10 ± 0.02 mm.

3.5 Environmental Compliance and Export Certifications

The product fully complies with the RoHS Directive and contains no lead, mercury, cadmium or other restricted substances. At the end of its service life, the product shall be disposed of in accordance with applicable waste electrical and electronic equipment requirements and shall not be discarded with general waste.



RoHS
Certified



FCC
Certified



Recyclable
Materials



CE
Certified



UKCA
Certified



WEEE
Certified

4 Core Technical Parameters

Parameter	Specification	Test Condition / Method	Remarks
Electrode Type	Ear-Worn Conductive Silicone Electrode	Normal temperature and pressure	Fits the cymba conchae / tragus area
Geometric Contact Surface Size	Per electrode: 1.2 cm × 0.8 cm (±0.1 cm)	Measure three points with a vernier caliper and calculate the average	Overall dimensional tolerance ≤ ±10%
Effective Conductive Area	Per electrode: ≥0.48 cm² (±0.05 cm²)	Measure the conductive area using a microscope	The central carbon-filled silicone is the effective conductive area. The insulating outer border is excluded
Conductive Impedance	80-350 Ω	1 kHz, 0.5-1 V small signal; place the two conductive surfaces in contact	Batch consistency: ±20%. Values outside the specified range are nonconforming
PCB Immersion-Gold Thickness	2 μm (±0.2 μm)	Coating thickness gauge	Ensures stable conductivity and wear resistance. A 1 μm finish is not permitted
Cable Specification	Multi-stranded copper conductor, cross-sectional area ≥0.05 mm²; cable length 50 ± 2 cm	Vernier caliper and multimeter	Cable resistance ≤0.5 Ω; no broken conductor or intermittent contact
Operating Temperature	5-40°C	Constant-temperature chamber	Suitable for consumer electronic operating environments
Operating Humidity	10%-90% RH, non-condensing	Temperature and humidity chamber	Sweat- and moisture-resistant, with no conductivity degradation
Service Life	≥500 effective uses, 20 minutes per use	Simulated wearing and compression test	No wear, conductivity failure or silicone detachment
2.35 mm Safety DC Connection Cable	5.5 × 2.35 mm plug; total cable length 1.2 m ± 2 cm; insertion life ≥1,000 cycles; AC 1500 V / 1 min dielectric withstand	Vernier caliper, insertion tester and dielectric withstand-voltage tester	SR strain relief, V-0 flame-retardant rating, DC 5 V input
Device Electrical Parameters	Rated voltage: DC 3.7 V; charging input: DC 5 V; insulation resistance ≥10 MΩ	500 V insulation resistance tester and dielectric withstand-voltage tester	Type BF floating configuration; designed with reference to IEC 60601-1

5 Test Standards and Methods

5.1 Impedance Test

- **Test Instrument:** Digital LCR meter.
- **Test Conditions:**
 - Ambient temperature: $23^{\circ}\text{C} \pm 5^{\circ}\text{C}$
 - Relative humidity: $40\% \pm 10\% \text{ RH}$
 - Test frequency: 1 kHz
 - Test level: 0.5–1 V small signal
- **Test Procedure:** Place the two conductive contact surfaces flat against each other and apply light pressure of 50–100 g/cm². Connect the electrodes to the LCR meter and record the impedance. Randomly inspect 10% of each lot. Measure each sampled unit three times and use the average value. A variation greater than $\pm 20\%$ is considered nonconforming.

5.2 Appearance and Dimensional Test

- **Visual Inspection:** Inspect the product under normal lighting. The silicone shall be free from burrs, bubbles and damage. The conductive area shall have no missing material or peeling. The PCB shall have no oxidation or exposed copper. The cable insulation shall have no damage, peeling or exposed conductors.
- **Dimensional Measurement:** Use a vernier caliper to measure the geometric contact surface and total cable length. Use a microscope to measure the effective conductive area. A dimensional deviation greater than $\pm 10\%$ is considered nonconforming.

5.3 Wear and Durability Test

Use a fixture to simulate actual wearing and compression. Each test cycle shall last 20 minutes, for a total of 500 cycles. After testing, the overall electrode structure shall show no deformation. The conductive silicone shall show no detachment or cracking. The internal conductors shall show no breakage or intermittent electrical contact.

5.4 Biocompatibility Test

The skin-contact silicone material of the finished electrode shall be tested by an accredited third-party laboratory and confirmed to be non-cytotoxic, non-irritating and non-sensitizing, in compliance with applicable biocompatibility safety requirements.

5.5 Environmental Adaptability Test

1. **Temperature Test:** Place the electrode in a constant-temperature chamber at 5°C and 40°C for 24 hours at each temperature. After returning the product to room temperature, the impedance shall remain within specification and the appearance shall show no deformation.
2. **Humidity Test:** Place the electrode in a temperature and humidity chamber at 23°C and 90% RH, non-condensing, for 48 hours. After testing, the impedance shall remain within specification and no oxidation is permitted.

6 Quality Acceptance Criteria

6.1 Sampling and Lot Disposition

Randomly inspect 10% of each production lot, with a minimum sample size of 30 units.

If one defective unit is found, double the sample size. If any defective unit is found during the doubled inspection, the entire lot shall be rejected.

6.2 Mandatory Acceptance Items

- **Appearance:** The product shall fully comply with the material and workmanship requirements specified in Sections 3.1 to 3.4.
- **Critical Dimensions:** The geometric contact surface, effective conductive area and total cable length shall remain within the specified tolerances.
- **Electrical Performance:** Conductive impedance shall remain within 80–350 Ω .
- **Mechanical Durability:** The wear and fatigue-compression tests shall meet the requirements specified in Section 5.3.

7 Packaging, Storage and Precautions

7.1 Packaging Requirements

- **Inner Packaging:** Each electrode shall be individually packed in a transparent PE self-sealing bag. The bag label shall clearly indicate the product name, model, production date and lot number.
- **Intermediate Packaging:** Pack 50 electrodes in one antistatic paper box. The box label shall indicate the lot number, finished-product quantity and company logo.
- **Outer Carton:** Bulk packaging shall provide adequate protection against moisture, compression and vibration to prevent physical damage to the electrodes and cables during transportation.

7.2 Storage Conditions

- **Storage Environment:** Store indoors in a dry, well-ventilated environment at -20°C to 60°C and 5%–95% RH, non-condensing.
- **Storage Requirements:** Keep away from direct sunlight, localized heat sources, strong magnetic fields and corrosive chemicals.
- **Shelf Life:** The shelf life is 12 months from the date of manufacture when stored in the unopened original packaging.

8 Notes

- This specification applies to the ear electrode supplied with the company's ear relaxation massage device. Production shall be carried out strictly in accordance with this specification.
- Any requirements not covered in this specification shall follow applicable industry standards.
- This electrode is a consumer electronic accessory and is not a medical device. It shall not be used for medical diagnosis or treatment.