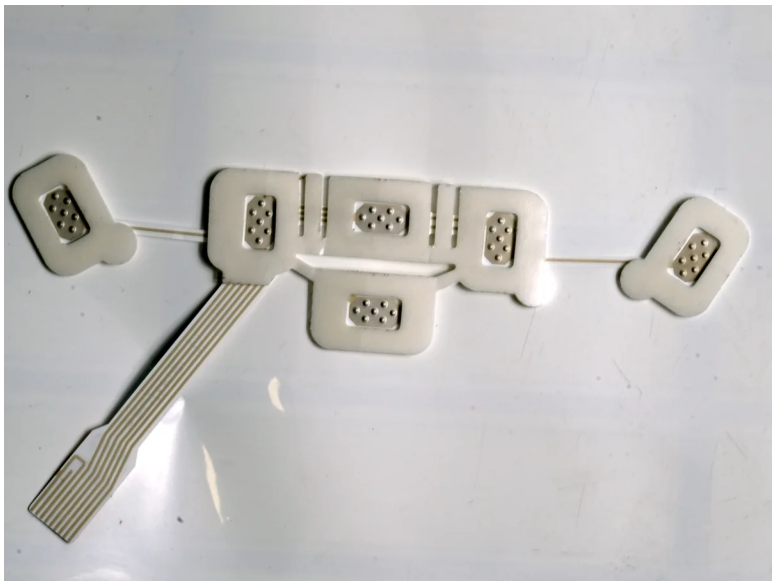
Printed Medical Electrode Component Checklist

Manufacturing inputs and responsibility boundaries for printed electrode arrays and patches.



Evidence basis: documented JASPER product or factory imagery supports physical manufacturing scope only. Project-specific results require project-specific records.

Component scope and boundary

This checklist covers printed electrode component manufacturing only. The finished medical-device manufacturer owns intended use, clinical claims, biocompatibility strategy, sterilization, packaging validation, regulatory submission, risk management, and final-device release.

[ ] Printed conductor/electrode geometry and routing are released by drawing.

[ ] Substrate, ink, gel/adhesive, liner, cable, connector, and packaging are identified.

[ ] Component acceptance is separated from clinical or diagnostic performance.

[ ] No biocompatibility, sterility, regulatory, or clinical result is inferred from a sample photo.

RFQ inputs

[ ] Dimensioned electrode pattern, sensing/stimulation areas, traces, tail, and cut profile.

[ ] Substrate, conductive ink, Ag/AgCl or other electrode system, and thickness requirements.

[ ] Skin-contact gel or adhesive, carrier, release liner, wear duration, and removal conditions.

[ ] Cable/connector/pinout, strain relief, mating interface, and electrical test method.

[ ] Cleanliness, handling, environment, shelf-life ownership, packaging, and labeling inputs.

[ ] Prototype/production quantities, test samples, traceability, change control, and approvals.

Responsibility matrix

Decision	Manufacturing evidence	Release owner
Geometry	Controlled artwork/drawing, dimensions, alignment, cut profile	Customer + JASPER per specification
Materials	Released BOM, identity/lot records, supplier documentation	Customer medical-device owner
Electrical	Defined component test method and results	Customer system/electrical owner
Skin contact	Specified adhesive/gel and manufacturing records	Finished-device biological safety owner
Clinical/regulatory	Not established by component manufacturing evidence	Legal finished-device manufacturer

Before production release

[ ] The approved sample is linked to drawing, artwork, BOM, process, and test revisions.

[ ] Material substitutions and supplier changes have a written notification route.

[ ] Acceptance limits and data ownership are explicit for every component test.

[ ] Packaging protects gel/adhesive, liner, cable, connector, and printed surfaces.

[ ] Finished-device validation requirements are not silently assigned to the component supplier.

Project review contact

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