

# JY Care — Face Mask Qualification Checklist

**\*See the Scoring Table** at the end of this document. Use it to assess the qualifications of manufacturing vendors to fulfill your requirements.\*

## Vendor First-Conversation Checklist

- ☐ Confirm markets of sale/use
- ☐ Request one recent ASTM test summary for the exact variant
- ☐ Ask how the vendor tracks a batch end-to-end
- ☐ Request honest lead times and MOQs
- ☐ If bio-additive: request method reference + scope and a no-impairment statement
- ☐ Send consolidated request email for the complete qualification pack

Buyers can paste this into an email to any mask supplier to collect all the documents needed for qualification in one shot. It compresses the full checklist into a single, actionable ask—so you don't trade back-and-forth emails.

"Please provide the variant-specific ASTM F2100 test summary (BFE, PFE,  $\Delta P$ , fluid resistance, flammability) for [Level / Color / Ear-loops], plus a report dated within 12 months or a no-change letter tied to the current BoM. Include GMP / ISO-8 / (FDA registration or listing, if applicable), a QMS overview with change-control policy, a lot-code example and sample batch record (redacted), label proofs, storage/shelf-life, throughput / MOQs / lead-time, and pallet / Incoterms / damage-claims process. If offering a bio-additive variant, also include the biodegradation method and conditions, additive identity / layer / % range, a no-impairment statement against ASTM F2100 performance, and the approved claim language you use."

## When to use

- First contact with a new supplier (or re-qualifying an old one).
- Anytime you need a complete ASTM pack + facility/QMS + commercial basics.
- Add the bio-additive sentence only if you're evaluating biodegradable variants.

## How to score the checklist.

### Gatekeepers (must pass):

- ☐ Facility & QMS present (GMP + ISO-8 + FDA registration/listing if relevant)
- ☐ ASTM evidence present for **exact** variant (BFE, PFE,  $\Delta$ P, fluid resistance, flammability)

Scoring scale per line item: **0 = Fail / Not provided, 1 = Meets, 2 = Exceeds**

Decision bands (total out of 16): **14–16 = GREEN, 11–13 = YELLOW,  $\leq 10$  = RED**

*(If either gatekeeper = 0  $\rightarrow$  automatic RED.)*

### 1) Facility & QMS (*Gatekeeper*)

- ☐ GMP certification/attestation
- ☐ ISO-8 cleanroom evidence
- ☐ FDA facility registration/listing (if applicable)
- ☐ QMS overview + SOP excerpts (change control, non-conformance/CAPA)
- ☐ Last 12-month change log (redacted allowed)

### 2) ASTM Evidence — Variant Specific (*Gatekeeper*)

- ☐ ASTM F2100 test summary for **this** variant (Level, colorway, ear-loop/nose wire): BFE, PFE,  $\Delta$ P, fluid resistance, flammability
- ☐ Report  $\leq 12$  months old **or** no-change letter tied to current BoM
- ☐ Labels exactly match the test summary (no over-reach)

### 3) Traceability & Change Control

- ☐ Lot code example + decoding key
- ☐ Sample batch record (redacted) **or** flow (ingredients  $\rightarrow$  WIP  $\rightarrow$  finished goods)
- ☐ Written change-control policy + triggers
- ☐ Customer change-notification process

## 4) Materials, Declarations & Safety

- ☐ Latex-free declaration
- ☐ Graphene-free declaration
- ☐ Biocompatibility / skin-contact note (where applicable)
- ☐ Colorant/pigment compliance statement (for colored masks)

## 5) Packaging, Labeling & Storage

- ☐ Pack formats listed (inner/outer/master); sterile vs non-sterile noted (if applicable)
- ☐ Label proofs (outer and unit) with barcodes
- ☐ Storage conditions and shelf life stated (basis referenced)

## 6) Capacity, MOQs & Lead Times

- ☐ Throughput stated (pcs/month)
- ☐ MOQ ranges stated
- ☐ Lead-time windows stated
- ☐ Surge/scale plan stated (if demand doubles)

## 7) Logistics & Commercial

- ☐ Incoterms stated
- ☐ Pallet specs provided
- ☐ Damage/claims process described
- ☐ Country-of-origin/customs notes (if needed)

## 8) Sustainability / End-of-Life — Bio-Additive SKUs only

- ☐ Named biodegradation method + conditions (environment, duration, endpoints)
- ☐ Additive identity, layer/location, and % range
- ☐ Statement that additive **does not impair** ASTM F2100 performance
- ☐ Copy guardrails used (“biodegradable additive used”, “observed under specified conditions...”)
- ☐ End-of-life guidance aligned with disposal environment/policy

## Attach these with every quote (ready list)

- [ ] Variant-specific ASTM summary (BFE, PFE,  $\Delta P$ , fluid resistance, flammability for the exact Level/variant)
- [ ] Freshness  $\leq$  12 months or no-change letter tied to current BoM
- [ ] Label proofs (outer and unit packs with barcodes)
- [ ] GMP / ISO-8 / FDA facility evidence (as applicable)
- [ ] QMS overview + change-control excerpt (policy and triggers)
- [ ] Lot code example + decoding key
- [ ] Sample batch record (redacted) or process flow (ingredients  $\rightarrow$  WIP  $\rightarrow$  finished goods)
- [ ] Throughput, MOQs, and lead-time windows
- [ ] Pallet specifications + Incoterms + damage/claims process
- [ ] Storage conditions and shelf life (basis stated)

## Bio-Additive add-on (if applicable)

- [ ] Named method + conditions (environment, duration, endpoints measured)
- [ ] Additive identity, layer/location, and % range in the mask construction
- [ ] No-impairment statement vs ASTM F2100 performance for this configuration
- [ ] Approved guardrail copy (“biodegradable additive used”; “observed under specified conditions...”)

## Scoring Table Section

### Reviewer quick steps

- [ ] **Gatekeepers first:** Facility & QMS, ASTM Evidence. If either = **0**, stop  $\rightarrow$  **RED**.
- [ ] **Score items:** **0 / 1 / 2** (Fail / Meets / Exceeds) or (Green / Yellow / Red).
- [ ] **Total:** out of **16**. If no bio-additive row, total out of **14**.
- [ ] **Decision:** **GREEN  $\geq 14$  • YELLOW 11–13 • RED  $\leq 10$**   
 Maximum Points = 16: **GREEN  $\geq 12$  • YELLOW 9–11 • RED  $\leq 8$**
- [ ] **Note gaps** needing to be filled in order to close before PO.

## Side-by-Side Score Table

**Instructions:** Enter **0, 1, or 2** for each vendor. Use **Notes** for filenames/links (e.g., Mask\_L3\_ASTM\_Summary.pdf). Gatekeepers must be **≥1**; if a gatekeeper = **0**, mark **RED**.

Criterion	Vendor A	Vendor B	Notes (file names/ref)
Facility & QMS ( <i>Gatekeeper</i> )			GMP, ISO-8, FDA (if applicable), QMS/SOPs, change log
ASTM Evidence ( <i>Gatekeeper</i> )			L1/L2/L3 summary: BFE, PFE, ΔP, fluid resistance, flammability; ≤12 months or no-change; labels aligned
Traceability & Change Control			Lot code sample, batch record/flow, policy + triggers, customer notification
Materials & Safety			Latex-free, graphene-free, biocompatibility note, pigment compliance (if colored)
Packaging / Labeling / Storage			Pack formats, label proofs (outer/unit), storage conditions + shelf-life basis
Capacity / MOQs / Lead Times			Throughput (pcs/month), MOQs, lead-time windows, surge/scale plan
Logistics & Commercial			Incoterms, pallet specs, damage/claims process, country of origin/customs
Sustainability / End-of-Life ( <i>Bio-Additive only</i> )			Method + conditions, additive identity/layer/% range, no-impairment, guardrail copy
<b>TOTAL (max 16)</b>			