Disposable Syringe Manufacturing

Medical-grade moulding, printing, assembly, packaging and validated sterilisation interface for disposable syringes.

Preliminary engineering range; excludes land, finance cost, taxes and import duty. Final scope and price are confirmed at the feasibility gate.

- Indicative CAPEX: USD 5–14M
- Delivery: 15–24 months to validated production and sterilisation release.
- Capacity: Tier 1: 30–80M syringes/year; Tier 2: 120–300M/year; two shifts, size mix and automation dependent.

Process flow

Preliminary basis for zoning, equipment and validation.

- Medical-grade polymer receipt and drying
- Barrel, plunger and component injection moulding
- Graduation printing and needle/component preparation
- Automated assembly and lubrication control
- Primary packaging and seal verification
- Sterilisation, residuals and functional release

Facility & clean environment

2,500–6,000 m² gross; 700–1,800 m² controlled moulding, assembly and packaging areas, typically ISO 8.

ISO 8 controlled assembly/packaging is typical. Moulding classification is based on open-product exposure and transfer design. Sterilisation loading is segregated from released goods.

- Substantial electrical load, chilled water, dry compressed air, HVAC, polymer handling, mould cooling, backup power and validated sterilisation/logistics route.

Equipment architecture

Vendor-neutral equipment classes; final URS is issued at feasibility.

- High-precision injection moulding and moulds
- Automated printing and assembly lines
- Vision inspection and leak/force testing
- Blister or pouch packaging equipment
- EO sterilisation interface or qualified outsourced sterilisation

Capacity & programme

Tier 1: 30–80M syringes/year; Tier 2: 120–300M/year; two shifts, size mix and automation dependent.

15–24 months to validated production and sterilisation release.

- Capacity assumes stated shifts, qualified inputs, maintenance and validated yield.

Quality & regulatory route

ISO 13485 QMS readiness; ISO 7886 product testing, biocompatibility, packaging and sterilisation validation as applicable. Facility readiness typically 12–20 months.

- Approval decisions remain with the competent independent authority.

Critical risks & staffing

Indicative 55–140 FTE; 8–16 weeks moulding, automation, quality and sterilisation training.

- Dimensional variation and leakage
- Graduation-print error
- Excess lubricant or particulate
- Needle attachment/force failure
- Package integrity or EO residual failure

Feasibility gate

Operating economics are issued as a sensitivity model using local labour, utilities, materials, yield, utilisation and financing assumptions; they are not a guaranteed return.

Provide country, site, portfolio, capacity, budget, financing and target date.

- Nigeria — syringe/medical-plastics production scope
- Azerbaijan — medical-plastics localisation programme
- Türkiye — syringe production engineering portfolio