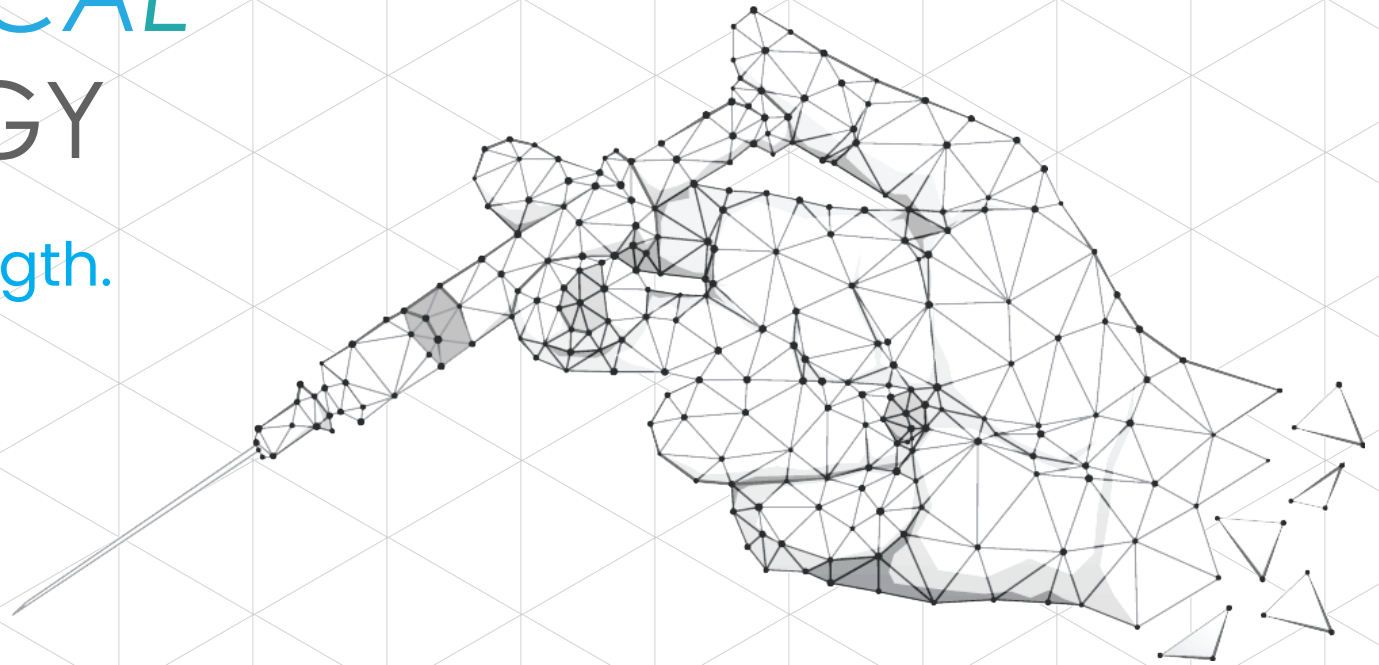




Company Profile 2026

# ALPHAMEDICAL TECHNOLOGY

Manufacturing Strength.  
Dependable Supply.



[WWW.ALPHAMT.ID](http://WWW.ALPHAMT.ID)

## ABOUT US

# Precision manufacturing for reliable healthcare.

PT Alpha Medical Technology is an Indonesian medical-device manufacturer dedicated to producing dependable products that support safe healthcare delivery. Under the Alphaject brand, we manufacture sterile hypodermic syringes for single use in multiple capacities and configurations, including Luer Slip, Luer Lock and auto-disable syringes.

Our manufacturing operations combine precision injection molding, barrel printing, automated assembly and primary packaging within controlled production environments. Supported by an ISO 13485-certified quality management system, we remain focused on product quality, regulatory compliance, continuous improvement and the needs of healthcare professionals.



## ABOUT US

## Company at a glance.

|                                |                                    |
|--------------------------------|------------------------------------|
| Location:                      | Cimmangis, Depok, Indonesia        |
| Manufacturing Products :       | Single-use Hypodermic Syringe      |
|                                | 1 mL, 3 mL, 5 mL and 10 mL         |
|                                | Luer Lock/ Luer Slip Syringe       |
|                                | Auto Disable Syringe               |
|                                | 0.05 mL, 0.5 mL and 3 mL           |
| Certifications:                | ISO 13485 certified quality system |
|                                | TKDN -certified products           |
|                                | FDA-510 K Cleared Medical Syringe  |
|                                | Cleanroom Certification            |
| Annual Capacity                | 250,000,000                        |
| Production Line                | 6                                  |
| Factory Floor Area             | 2,500 m <sup>2</sup>               |
| Number of products holding AKD | 10                                 |



## OUR VISION

**To become a trusted Indonesian medical-device manufacturer recognized for safe products, consistent quality and reliable supply.**

**01****Product safety**

support the intended use of every approved configuration.

**02****Consistent quality**

Documented inspection and release decisions support repeatable production.

**03****Dependable supply**

Production planning and distribution coordination serve recurring customer demand.

**04****Continuous improvement**

Teams track operating performance and correct recurring process losses.



## OUR JOURNEY

# Building a trusted medical-device manufacturing in Indonesia.

**Company  
Established**  
Sept 2023

**First Production  
Line Installed**  
June 2024

**First AKD Product  
Registration**  
Aug 2025

**Commercial  
Launch of Alphaject**  
Dec 2025

**Factory  
Development**  
May 2024

**ISO 13485  
Certification**  
Nov 2024

**FDA  
Establishment  
Registration**  
Nov 2025

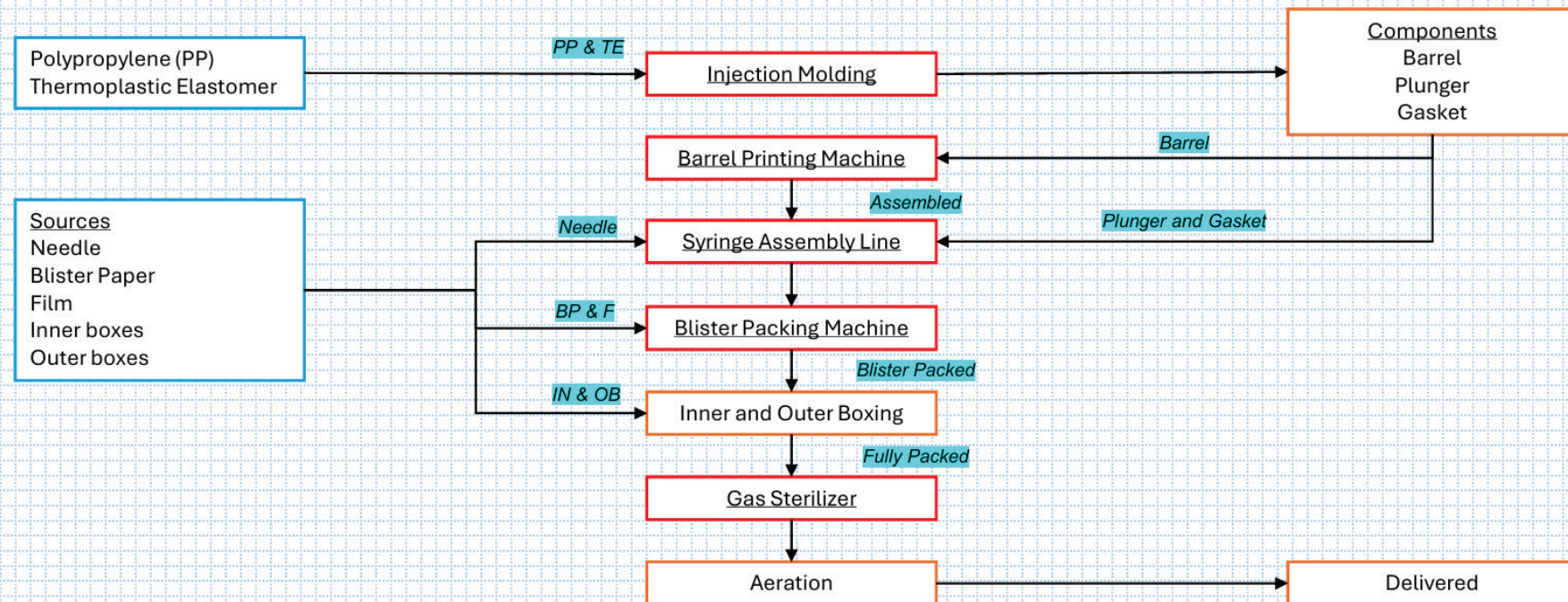
**TKDN  
Certification**  
June 2026



# MANUFACTURING

## Production Process Flow

The production process begins with polypropylene and thermoplastic elastomer being injection moulded into syringe barrels, plungers and gaskets. The barrels are printed and then combined with the plungers, gaskets and supplied needles on the automated assembly line. Assembled syringes are individually sealed using blister paper and film before being packed into inner and outer cartons. The completed products undergo validated EO gas sterilization and aeration before final quality release and delivery

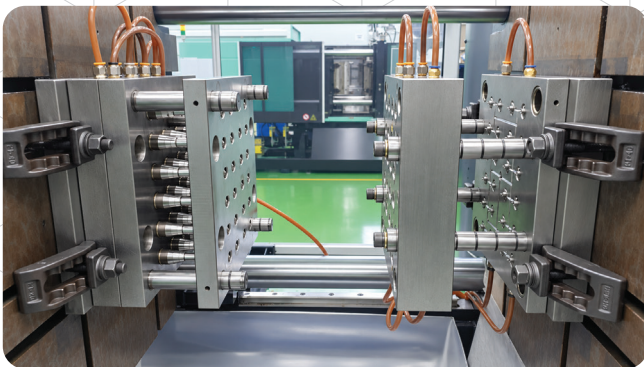
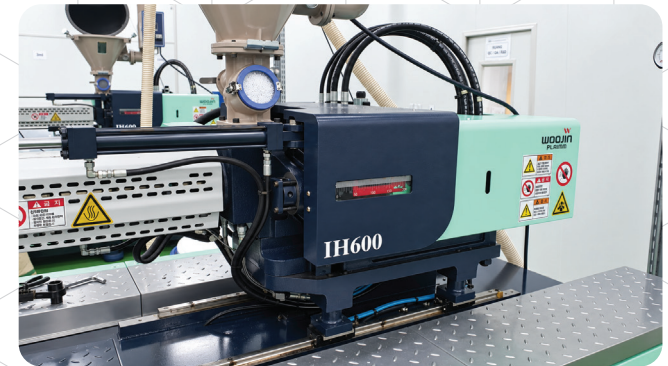


# MANUFACTURING

## Precision Injection Molding

recision injection moulding transforms specified polypropylene and thermoplastic elastomer materials into syringe barrels, plungers and gaskets. Critical machine parameters—including material temperature, injection pressure, holding pressure, cooling time and cycle time—are controlled to achieve consistent dimensions and surface quality. Each production batch undergoes in-process inspection before the components are released for printing and assembly.

- Production of syringe barrels, plungers and elastomer gaskets
- Controlled temperature, injection pressure, holding pressure and cooling time
- Dedicated multi-cavity moulds for different syringe capacities
- High-volume production using moulds with up to 124 cavities
- In-process dimensional and visual component inspection
- Raw-material and production-batch traceability
- Preventive mould maintenance and approved machine setup procedures
- Process monitoring to support consistent component quality

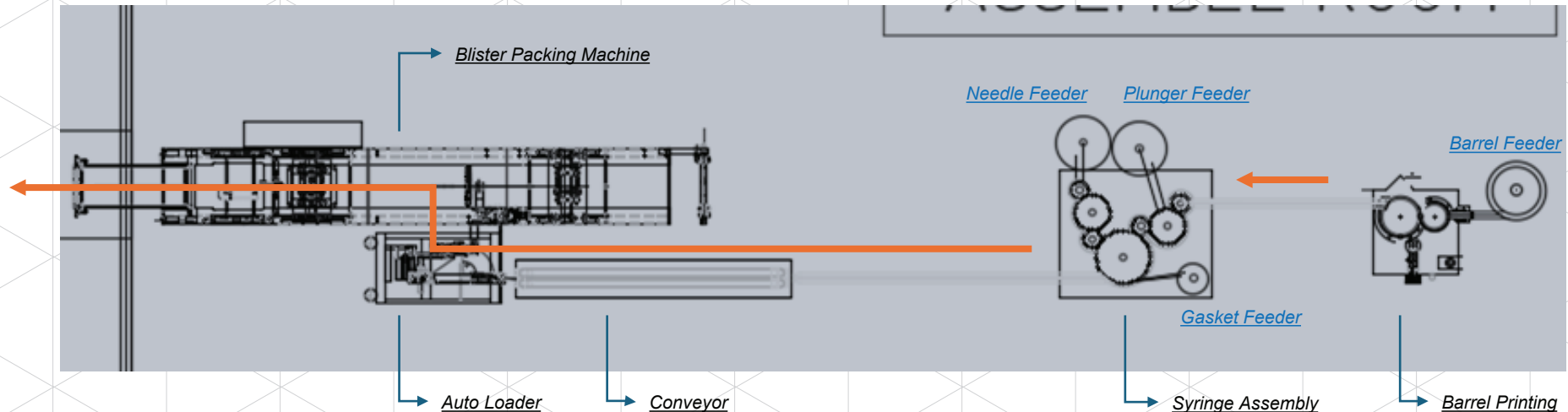
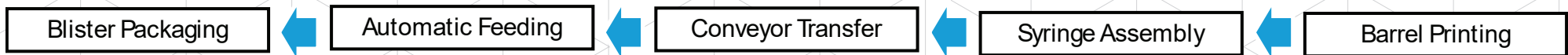


# MANUFACTURING

## Fully Automated Inline Production

The fully automated inline production line integrates barrel printing, syringe assembly and blister packaging into one continuous process. After assembly, finished syringes are transferred by conveyor to an automatic feeder, which aligns and delivers each syringe directly into the blister-packaging machine. This synchronized system supports consistent production flow, reduces unnecessary manual handling and improves efficiency from printed components through individually sealed primary packaging.

- Continuous production flow from barrel printing through primary blister packaging
- Automated assembly of the barrel, plunger, gasket and needle
- Conveyor transfer of assembled syringes between production stages
- Automatic feeder aligns and loads syringes into the blister-packaging machine
- Reduced manual handling and unnecessary product contact
- Synchronized equipment speeds support consistent production flow
- Faster processing and improved production throughput
- Batch traceability maintained throughout printing, assembly and packaging

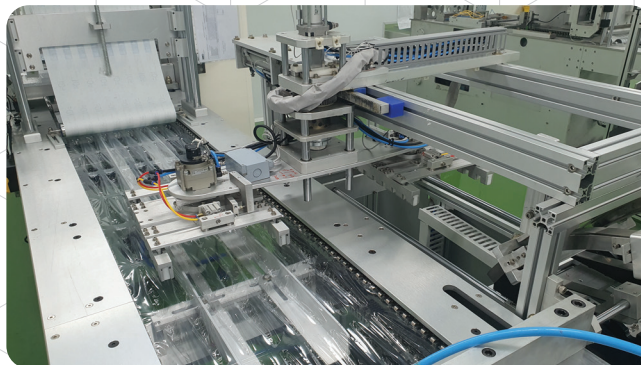
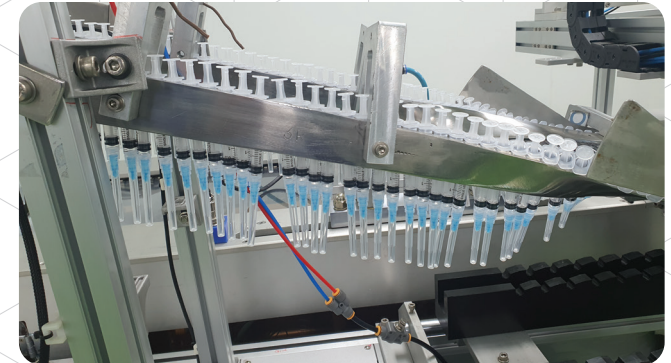


# MANUFACTURING

## Automated Blister Packing

Finished syringes are individually packed using automated blister-packaging systems. Controlled forming and sealing parameters help protect product integrity and create a secure sterile-barrier package for subsequent sterilization. Automated handling improves packaging consistency while reducing unnecessary product contact. Integrated inspection supports correct positioning, seal quality and packaging traceability.

- Automatic syringe feeding and alignment
- Continuous blister forming, sealing and cutting
- Controlled sealing temperature, pressure and dwell time
- Compatible with multiple syringe sizes and packaging formats
- Reduced manual handling during primary packaging
- Consistent blister dimensions and seal positioning
- In-process inspection of seals, product position and packaging materials
- Individual sterile-barrier packaging prepared for EO sterilization
- Batch identification and packaging traceability



# MANUFACTURING

## Primary Packaging

Each assembled syringe is automatically positioned and heat-sealed within an individual blister using forming film and medical-grade paper. Controlled sealing parameters support package integrity and allow EO gas penetration during sterilization. The blister-packed syringes are then arranged in product-specific inner boxes and master cartons to support identification, handling, storage, transportation and distribution.



|             | Carton | Innerbox | Master Box Dimensions |     |     | Inner box Dimensions |     |     |
|-------------|--------|----------|-----------------------|-----|-----|----------------------|-----|-----|
| Type        | pcs    | pcs      | L                     | W   | H   | L                    | W   | H   |
|             |        |          | mm                    | mm  | mm  | mm                   | mm  | mm  |
| 1ML - DSLS  | 1800   | 100      | 506                   | 385 | 281 | 190                  | 167 | 92  |
| 3ML - LS    | 1200   | 100      | 545                   | 405 | 305 | 200                  | 180 | 150 |
| 3ML - LL    | 1200   | 100      | 545                   | 405 | 305 | 200                  | 180 | 150 |
| 5ML- LS     | 1200   | 100      | 545                   | 405 | 345 | 200                  | 180 | 170 |
| 5ML- LL     | 1200   | 100      | 545                   | 405 | 345 | 200                  | 180 | 170 |
| 10ML- LS    | 600    | 50       | 545                   | 405 | 345 | 200                  | 180 | 176 |
| 10 ML -LL   | 600    | 50       | 545                   | 405 | 345 | 200                  | 180 | 176 |
| 0.05 ML ADS | 1800   | 100      | 506                   | 385 | 281 | 190                  | 167 | 92  |
| 0.5 ML ADS  | 1200   | 100      | 506                   | 385 | 281 | 190                  | 167 | 92  |
| 3 ML ADS    | 1200   | 100      | 545                   | 405 | 305 | 200                  | 180 | 150 |

# CLEANROOM

## Controlled Manufacturing Environment.

Finished syringes are individually packed using automated blister-packaging systems. Controlled forming and sealing parameters help protect product integrity and create a secure sterile-barrier package for subsequent sterilization.

- ISO 7 controlled production areas
- ISO 8 Injection Room
- HEPA-filtered air supply
- Positive-pressure control
- Temperature and humidity monitoring
- Environmental monitoring
- Personnel gowning procedures
- Controlled material and personnel movement
- Cleaning and sanitation programs
- Preventive maintenance



*Six Person Air Shower*



*Air Handling Unit 65 RT*

# CLEANROOM

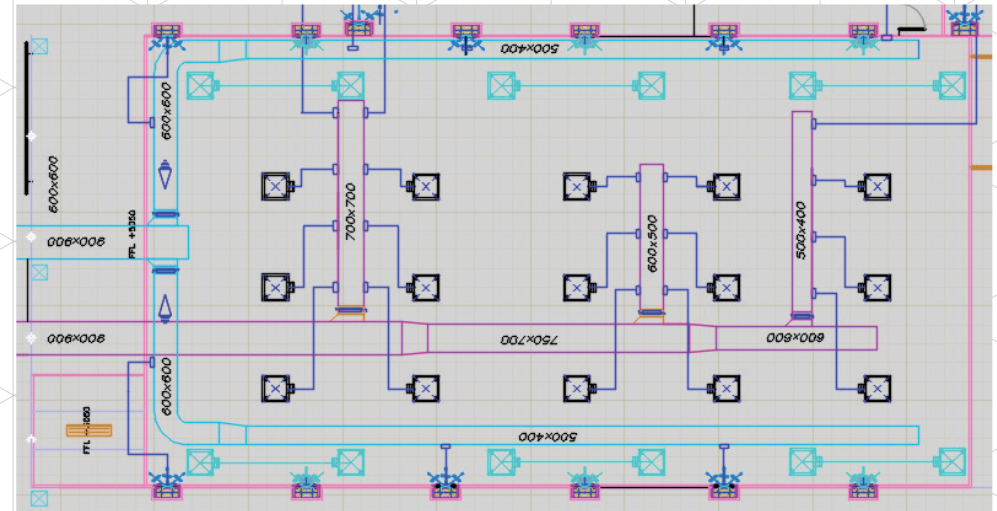
## Controlled Manufacturing Environment.



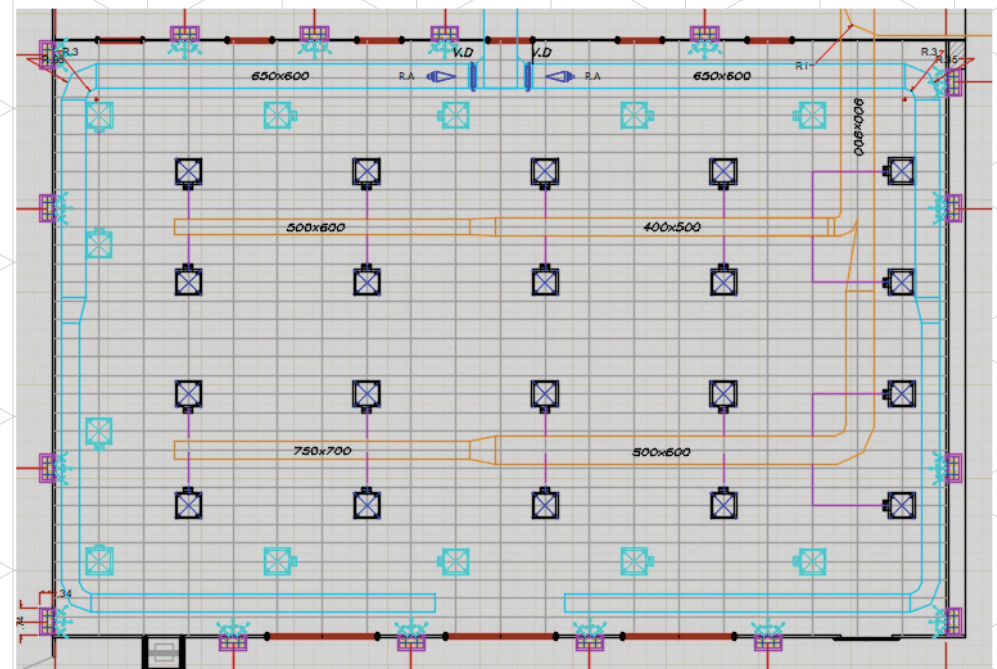
*Injection Room - ISO 8 Cleanroom*



*Production Room - ISO 7 Cleanroom*



*Injection Room HEPA Filter Layout - 27 HEPA Filters*



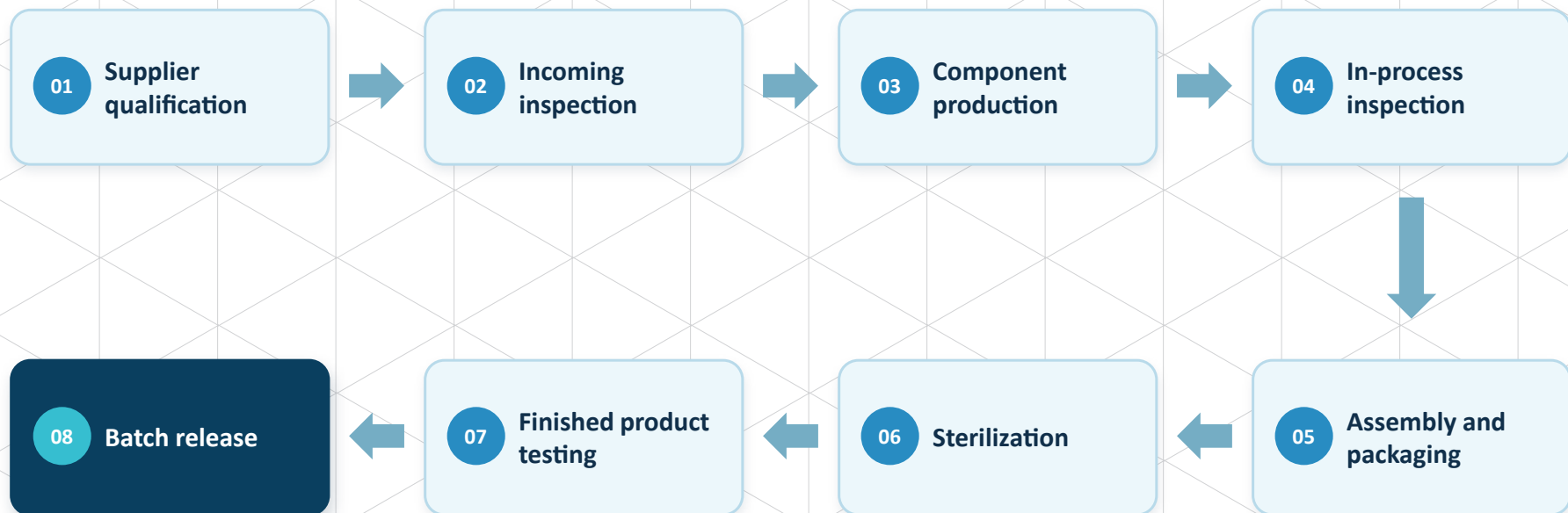
*Production Room HEPA Filter Layout - 32 HEPA Filters*

# QUALITY MANAGEMENT

## Quality-Controlled Process Flow

Operating under our ISO 13485 quality management system, quality is controlled throughout the production process—from supplier qualification and incoming inspection to component production, assembly, packaging and sterilization. Documented procedures, equipment calibration, process validation and material traceability support every stage. Finished products undergo final testing and batch-record review before release by authorized quality personnel.

- ISO 13485 quality management system
- Document and record control
- Material traceability
- Supplier qualification
- Equipment calibration
- Process validation
- Nonconformance control
- CAPA
- Complaint handling
- Batch release by authorized quality personnel



Quality Process Flow

# QUALITY MANAGEMENT

## Product Testing and Compliance.

| Registration or certificate | Description                                                        |
|-----------------------------|--------------------------------------------------------------------|
| Indonesian AKD registration | AKD registration number for each registered product                |
| TKDN certification          | TKDN percentage and certificate number for each applicable product |
| CPAKB certification         | CPAKB Registration number for factory.                             |

| Credential or status           | Description                                                              |
|--------------------------------|--------------------------------------------------------------------------|
| ISO 13485 certification        | Certificate number, certification body and validity period               |
| FDA establishment registration | Establishment registration or FEI number and current registration status |

| Standard         | Application                                                              |
|------------------|--------------------------------------------------------------------------|
| ISO 7886-1       | Manually operated sterile syringes for single use                        |
| ISO 7886-3       | Fixed-dose auto-disable syringes                                         |
| ISO 7886-4       | Syringes with reuse-prevention features                                  |
| ISO 80369-7      | Small-bore Luer connectors for intravascular and hypodermic applications |
| ISO 7864         | Sterile hypodermic needles for single use                                |
| ISO 10993 series | Biological evaluation of medical-device materials                        |

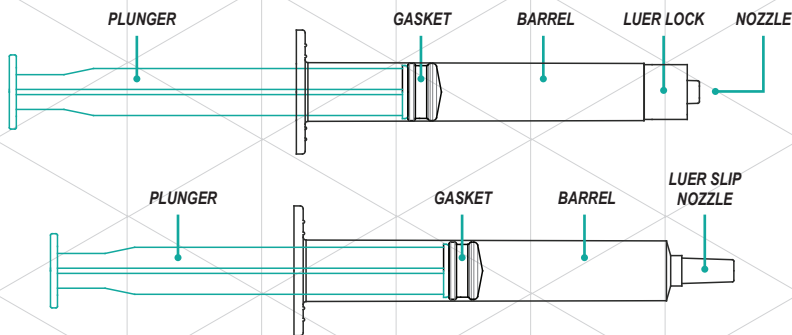
| Test capability                      | Purpose                                                      |
|--------------------------------------|--------------------------------------------------------------|
| Graduation accuracy                  | Confirms the accuracy and readability of the graduated scale |
| Leakage testing                      | Evaluates air and liquid leakage during use                  |
| Plunger movement and operating force | Measures break-loose force and smooth plunger movement       |
| Dead-space evaluation                | Measures the residual volume remaining after injection       |
| Luer connection performance          | Evaluates connector dimensions, fit, security and leakage    |
| Packaging seal integrity             | Confirms seal consistency and sterile-barrier integrity      |

PRODUCT PORTFOLIO

Sterile Hypodermic Syringes

ISO 7886-1 • ISO 80369-7 • STERILE EO • SINGLE USE

Sterile hypodermic syringes for single use are designed for medication delivery and fluid withdrawal. Multiple capacities and Luer connections support appropriate selection across clinical procedures and applications. Clear barrels and legible graduations support accurate, controlled dose measurement.



1 ml Luer Slip



3 ml Luer Lock



5 ml Luer Lock



10 ml Luer Lock

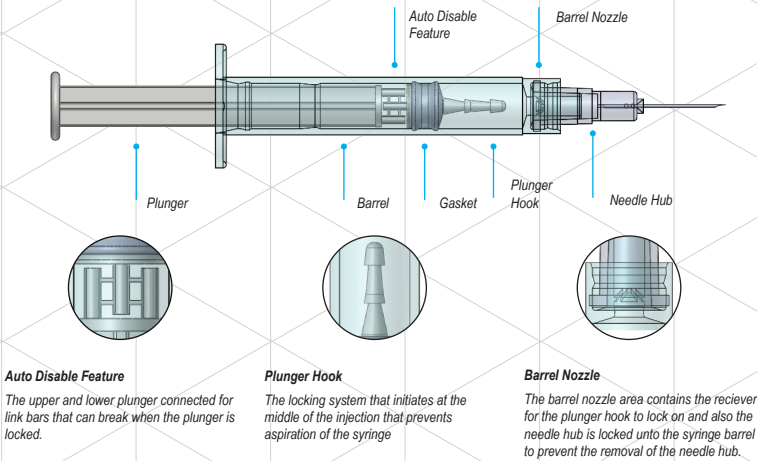
| Nominal Capacity | 1 ML                                              | 3 ML                                              | 5 ML                                                   | 10 ML                                             |
|------------------|---------------------------------------------------|---------------------------------------------------|--------------------------------------------------------|---------------------------------------------------|
| Connection       | Luer Slip                                         | Luer Slip / Luer Lock                             | Luer Slip / Luer Lock                                  | Luer Slip / Luer Lock                             |
| User Profile     | Fine volume preparations and administration       | Routine medical delivery and aspiration           | Administration of larger prescribed medication volumes | Withdrawal and transfer of larger liquid volumes  |
| Needle Options   | According to approved commercial satisfaction     | According to approved commercial satisfaction     | According to approved commercial satisfaction          | According to approved commercial satisfaction     |
| Packaging        | Individually blister packed - single used syringe | Individually blister packed - single used syringe | Individually blister packed - single used syringe      | Individually blister packed - single used syringe |
|                  | 1 innerbox - 100 pcs                              | 1 innerbox - 100 pcs                              | 1 innerbox - 100 pcs                                   | 1 innerbox - 100 pcs                              |
|                  | 1 masterbox - 1800 pcs                            | 1 masterbox - 1200 pcs                            | 1 masterbox - 1200 pcs                                 | 1 masterbox - 1200 pcs                            |

# PRODUCT PORTFOLIO

## Auto Disable Syringes

ISO 7886-3 • AUTO DISABLE • STERILE EO • SINGLE USE

Designed for fixed-dose immunization, the Alphaject Auto-Disable Syringe incorporates an integrated mechanism that automatically prevents reuse after the intended injection. Its precise dose capacity supports consistent vaccine administration, while the single-use design helps reduce the risks of syringe reuse and cross-contamination. Each syringe is supplied sterile and individually packaged for use by trained healthcare professionals.



### Usage Instruction



PUSH



LOCK



PULL



BREAK

| TYPE                        | SIZE                  | NEEDLE SIZE | PACKING TYPE                   | PACKING INNER     | PACKING OUTER     |
|-----------------------------|-----------------------|-------------|--------------------------------|-------------------|-------------------|
| AD Syringe<br>Fixed Dose    | Fixed Dose<br>0.05 cc | All Sizes   | Single Unit Blister<br>Packing | 100 pc / innerbox | 1800 pcs / carton |
| AD Syringe<br>Fixed Dose    | Fixed Dose<br>0.5 cc  | All Sizes   | Single Unit Blister<br>Packing | 100 pc / innerbox | 1200 pcs / carton |
| AD Syringe<br>Variable Dose | Variable Dose<br>3 cc | All Sizes   | Single Unit Blister<br>Packing | 100 pc / innerbox | 1200 pcs / carton |

TKDN

## Strengthening Indonesia's Medical Device Industry

Through domestic manufacturing and continued investment in production capability, PT Alpha Medical Technology contributes to the development of Indonesia's medical-device industry. Alphaject products with verified TKDN values support local procurement requirements while helping strengthen national supply resilience.



## PARTNERSHIPS

# Manufacturing Strength. Dependable Supply.

01



## Hospitals & Procurement

Reliable access to locally manufactured, sterile single-use syringes. We support hospitals and procurement organizations with consistent supply planning, product documentation, traceability and delivery coordination aligned with approved institutional requirements.

02



## Distributors

Scalable supply supported by dependable lead times, coordinated inventory planning, product information and responsive commercial service. Our distributor partnerships extend market reach while maintaining consistent product quality and customer support.institutional requirements.

03



## OEM & Private Label

Flexible OEM and private-label solutions tailored to agreed product specifications, packaging formats, branding requirements and order volumes. Support can extend from product configuration and packaging development through production, sterilization and final release.



## CONTACT US

# Let's build a dependable partnership.

For product inquiries, procurement discussions, distribution opportunities, or OEM and private-label projects, connect with our team.



PT ALPHA MEDICAL TECHNOLOGY

**Manufacturing Strength.**  
**Dependable Supply.**

## Start a conversation...

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