Industrial Development Authority
الهيئة العامة للتنمية الصناعية

EGYPTIAN DRUG AUTHORITY

Technical Requirements for Licensing Factories of Medical Devices,Laboratory and Diagnostic Reagents,Prosthetic Limbs, Orthotic Devices, and Mobility Aids

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First Scope of Application

These requirements apply to any facility producing medical devices, laboratory and diagnostic reagents, and manufacturing or assembling prosthetic limbs, orthotic devices, and mobility aids, as follows:

1. Factories producing non-sterile medical devices (e.g., oxygen masks, ventilator circuits, medical devices, Personal Protective Equipment (PPE) / non-sterile medical clothing).
2. Factories producing non-sterile medical devices that are sterilized prior to use (e.g., medical plates and screws, medical clothing intended for sterilization).
3. Factories producing sterile medical devices (e.g., surgical joints, medical syringes, administration sets, surgical gloves, sterile medical clothing).
4. Factories producing laboratory and diagnostic reagents.
5. Factories producing prosthetic limbs, orthotic devices, and mobility aids (requirements applicable to prosthetic limbs, orthotic devices, and mobility aid factories apply).
6. Factories producing medical devices in pharmaceutical dosage forms (e.g., drops, nasal sprays, gels, creams, powders, ampoules, vials, prefilled syringes). Good Manufacturing Practice (GMP) requirements issued by World Health Organization (WHO) apply.

Second Classification of Medical Devices

- According to European Union Medical Device Directive (EU-MDD Annex VII):
    a. Class I: Is (sterile condition), Im (measuring function), I (non-sterile).
    b. Class IIa.
    c. Class IIb.
    d. Class III.

- According to US Food and Drug Administration (FDA):
    a. Class I.
    b. Class II.
    c. Class III.

Third General Site Requirements

General site requirements apply to all manufacturing facilities and assembly centers for prosthetic limbs, as follows:

1. Manufacturing zone must have independent, dedicated entrances and exits.
2. No factory located within multi-story industrial complex shall be approved if any production step is carried out in Cleanroom Classified Area.
3. Presence of clear signage displaying factory name.
4. Minimum height from factory floor to ceiling soffit is 2.60 meters.
5. Factory floor must be at same level as, or higher than, street level. An exception may be granted provided that adequate precautions are taken to prevent water seepage into ground floors below street level, including installation of drainage network at appropriate distance to prevent contamination.
6. Uninterrupted Power Supply (UPS) is recommended for operations or processes requiring continuous power.
7. Separate production area for medical devices must be provided if another industrial activity exists onsite (applicable to non-sterile medical devices).
8. Compliance with Occupational Health and Safety (OHS) and fire prevention requirements according to Decree No. 864 of 2018.

Fourth Technical Requirements

1. Licensing Requirements for Factories Producing Non-Sterile Medical Devices

Requirements apply to factories producing non-sterile medical devices that do not require cleanroom production or packaging areas unless stipulated by manufacturing standards.

Factory Technical Requirements:

1. Restrooms—if present—must be separated from changing rooms, with restrooms located prior to Gowning Area.
2. Provision of open shoe racks; dedicated rack for street shoes and separate rack for restroom shoes (if applicable).
3. Provision of ventilation source in restrooms (if present).
4. Installation of air curtains and Electronic Insect Killers (EIK) at all factory entrances facing street directly.
5. Use of rust-proof stainless steel insect screens on all ventilation openings.
6. Separation of street shoes from internal factory footwear.
7. Separation of workers' outer clothing from factory-specific uniforms.
8. Provision of ventilation source.

Note: In case of medical supplies that include water in their composition, Water Treatment System meeting technical specifications shall be provided (Example: non-sterile ultrasound gel).

Facilities and Infrastructure

Warehouses:

- In case of single storage area, warehouse space must be designed according to nature of product and internally partitioned into separate zones with intermediate or physical separation.
- Warehouses are partitioned into following areas: ((According to nature of final product and production components.))
    - » Receiving Area.
    - » Raw Materials Storage Area.
    - » Packaging Materials Storage Area.
    - » Rejection Area for final product; must be tightly sealed and secured.
    - » Final Product Storage Area.
    - » Storage area for any raw materials or products requiring special storage conditions.

The following requirements apply:

1. Covered loading/unloading area must be provided to protect products or raw materials from sunlight and weather changes during transit to and from warehouses.
2. Adequate ventilation must be maintained.
3. Temperature and humidity gauges must be installed, ensuring ranges are suitable for nature of product.
4. Floors must be durable and robust (e.g., helicopter-finished concrete).
5. Rodent control program must be implemented.
6. All warehouse doors must be tightly sealed to prevent entry of dust or insects.
7. Ventilation openings must be fitted with fine mesh wire, and glass surfaces treated (e.g., opaque/tinted) to prevent direct sunlight exposure.
8. No water source shall be present within storage area.
9. Storage directly on floor is prohibited; pallets or racks compliant with Good Storage Practices (GSP) and industrial safety requirements must be used. Storage must maintain clearance of 60 cm from ceiling soffit and 20 cm from walls.

Note: If separate warehouse for final product exists, all above-mentioned requirements must be met.

Production Areas

Worker Preparation Area (prior to entering production zones, according to medical device production standards):

1. Unclassified Area (non-air-classified).
2. Workers must wear factory garments, head covers, and shoe covers at minimum.
3. f workers change clothing and shoes, Personnel Lockers must be provided to separate street clothes and shoes from factory-specific clothing, sized appropriately for worker count.
4. Adequate ventilation must be provided.
5. Hand disinfectant must be provided.
6. Walls and floors must be durable with smooth surfaces.
7. Pictorial Standard Operating Procedures (SOPs) must be displayed for pre-entry procedures to production area.

Production Area:

- Products are manufactured, assembled, and packaged within this area, which must comply with following requirements:

1. Unclassified Area (non-air-classified).
2. Area must be dedicated solely to production.
3. If water is used during production, its entry and exit paths to/from machinery must be Closed Loop System.
4. Adequate ventilation must be provided to maintain temperature and humidity levels suitable for nature of product.
5. Temperature and humidity gauges must be installed.
6. For anesthesia and respiratory devices, ventilation must be indirect (well-ventilated; use of fans is prohibited).
7. Floors must be durable, smooth, and clean (e.g., tiles or epoxy coatings).
8. Dedicated area for storing molds and dies must be provided, if required.

Laboratories (divided according to nature of final product):

A. Physicochemical Laboratory:

- Laboratory must be located in separate room, with following considerations:
  - » Space must be adequate for worker count, activity type, and scale.
  - » Suitable storage area for chemicals must be provided, ensuring storage follows instructions on labels.
  - » Laboratory Safety Measures must be observed.
  - » Laboratory must be equipped with necessary instruments according to medical device type; all instruments must undergo Calibration.
- If physicochemical testing of product is performed during manufacturing steps, separate laboratory room may be waived and considered part of production areas.
- Contract Testing with external laboratory is permitted.

B. Microbiological Laboratory:

- Contract Testing with external laboratory under supervision of Egyptian Drug Authority (EDA) is permitted if manufacturer requires specific microbiological tests.

2. Requirements for Licensing Factories Producing Non-Sterile Medical Devices Sterilized Prior to Use (e.g., medical plates and screws, textile-based medical products intended for sterilization)

These are factories producing non-sterile medical devices intended for sterilization before use (Ready to be Sterilized by user). Production is not required to be within cleanroom; however, packaging must be performed inside Classified Cleanroom.

A. Requirements for Factories Producing Textile-based Medical Devices Intended for Sterilization

Technical Requirements for Factory:

1. Restrooms—if present—must be separated from changing rooms, with restrooms located prior to Gowning Area.
2. Provision of open shoe racks; dedicated rack for street shoes and separate rack for restroom shoes (if applicable).
3. Provision of ventilation source in restrooms (if present).
4. Installation of air curtains and Electronic Insect Killers (EIK) at all factory entrances facing street directly.
5. Use of rust-proof stainless steel insect screens on all ventilation openings.
6. Separation of street shoes from internal factory footwear.
7. Separation of workers' outer clothing from factory-specific uniforms.

Facilities and Infrastructure:

Warehouses

In case of single warehouse, space must be adequate according to nature of product and internally partitioned into separate zones with physical or spatial separation.
Warehouses are partitioned into following areas (according to nature of final product and production components):

- Receiving Area.
- Raw Material Storage Area.
- Packaging and Primary Material Storage Area.
- Rejection Area for final product; must be secured and tightly closed.
- Finished Product Storage Area.
- Storage Area for any raw materials or products requiring special storage conditions.

The following requirements apply:

1. Covered area must be provided to ensure products or raw materials are protected from sunlight and weather changes during loading and unloading to and from warehouse.
2. Receiving area must be available for cleaning outer packaging of raw materials; this area must have ventilation source and Exhaust Fan.
3. Adequate ventilation must be maintained.

4. Temperature and humidity gauges must be installed, ensuring ranges are suitable for nature of product.
5. Floors must be durable and robust (e.g., helicopter-finished concrete).
6. Rodent control program must be implemented.
7. All warehouse doors must be tightly sealed to prevent entry of dust or insects.
8. Ventilation openings must be fitted with fine mesh wire, and glass surfaces treated (e.g., opaque/tinted) to prevent direct sunlight exposure.
9. No water source shall be present within storage area.
10. Products must not be stored directly on floor; pallets or racks compliant with Good Storage Practices (GSP) and industrial safety requirements must be used. Storage must maintain clearance of 60 cm from ceiling soffit and 20 cm from walls.

Note: In case of separate warehouse for finished product, all previously mentioned requirements must be fully implemented.

Production Areas

Gown Control Area (Controlled Area):

1. Unclassified Area (non-air-classified).
2. Lockers must be provided for both clothing and shoes, sized appropriately for worker count, along with Step-over Bench made of coated metal or stainless steel.
3. Dedicated Gowning Area(s) must be provided for workers.
4. Workers must change into area-specific footwear before entering designated zone.
5. Workers' outer clothing must be separated from area-specific clothing.
6. Ventilation source must be available.
7. Handwashing sinks must not be installed; hand disinfectant must be provided.
8. Walls and floors must be durable with smooth surfaces (Stout, Smooth).
9. Ventilation must be adequate and indirect (use of fans is prohibited); lighting must be sufficient and covered.
10. Standard Operating Procedures (SOPs) must be displayed, detailing worker entry procedures into controlled area.

Controlled Room

- This area is designated for cutting and sewing fabric; the following requirements apply

1. Controlled Room must be separate from other production zones.
2. Preparation area must be provided for cleaning and removing outer packaging of raw materials before entering Controlled Room. This area must be equipped with ventilation source and Exhaust Fan.
3. Controlled Room must have indirect ventilation (well-ventilated; use of fans is prohibited).
4. Temperature and humidity gauges must be installed inside Controlled Room, ensuring compliance with specific temperature and humidity requirements according to product specifications and Material Safety Data Sheet (MSDS).
5. Floors must be durable, smooth, and clean (e.g., tiles or epoxy coatings).
6. Non-direct ventilation system must be provided, including supply and return air networks.
7. When products are transferred from Controlled Room to Cleanroom, following must be observed:
    a. Products must be placed in double bags and transferred to Cleanroom through Classified Airlock or Dynamic Pass-through Box.
    b. Products must be stored in intermediate warehouse compliant with Good Storage Practices (GSP) requirements.

Secondary Gowning Area:

This area is designated for changing clothes prior to entering Cleanroom.

- Workers must change clothing, pass over Step-over Bench, and put on cleanroom garments (Secondary Gowning).
- Doors must be Interlocked (synchronized closing).
- Area must be classified as Class D / ISO 8.
- Cascading of Pressure: Install differential pressure gauges to ensure:

  Pressure differential between adjacent cleanrooms or clean zones of different cleanliness levels should lie typically in range of 5 Pa to 20 Pa, to allow doors to be opened and to avoid unintended cross-flows due to turbulence.
- Pressure differential between adjacent rooms of differing cleanliness levels must be maintained between 5–20 Pa to allow doors to open while preventing cross-contamination.

  i.e.: Between rooms of different grades, pressure differential should be approximately (10–15) ± 5 Pa.
- Air Grilles must not be office-type.
- Standard Operating Procedures (SOPs) must be displayed, detailing worker entry procedures into Cleanroom.

Cleanroom:

Medical Device Packaging Area

- Pressure Cascading must be maintained by installing Differential Pressure Gauges to ensure:
  - The pressure differential between adjacent cleanrooms or clean zones of different cleanliness level should lie typically in the range of 5 Pa to 20 Pa, to allow doors to be opened and to avoid unintended cross-flows due to turbulenc1e.
- Differential pressure between adjacent rooms of differing cleanliness levels must be maintained between 5–20 Pa, allowing doors to open while preventing unintended cross-contamination.

  i.e.: Between rooms of different grades, pressure differential should be approximately (10–15) ± 5 Pa.
- Doors must open towards cleaner area, in direction of higher Positive Pressure.
- Floors must be durable and smooth (e.g., epoxy or vinyl).
- Walls must be smooth; junction between walls and floors must be curved (Coving).
- Temperature and humidity must be controlled: 22°C ± 2°C and 65% ± 5% (conditions supporting minimal bacterial growth unless other technical requirements apply).
- Differential Pressure Gauges must be installed at all doors and Dynamic Pass Boxes in Cleanroom.
- Supply Air Grilles must be installed in ceiling; Return Air Grilles must be installed in ceiling or side walls. If Return Air Grilles are on side walls, they must be positioned at appropriate distance to ensure proper air recirculation.
- Air Grilles must not be office-type.
- Ceiling height must not be less than 2.60 m from floor.
- Air Change Rate (ACR) must be between 15–20 air changes per hour, in accordance with ISO 14644. Number of air changes range between 15–20/h.

Laboratories (Divided According to Nature of Final Product):

A. Physicochemical Laboratory:

- Laboratory must be located in separate room, with following considerations:
  - » Space must be appropriate for personnel count, activity type, and scale of operations.
  - » Suitable storage area for chemicals must be provided; storage must follow instructions indicated on containers.
  - » Safety measures within laboratory must be observed.
  - » Laboratory must be equipped with all necessary instruments according to medical device; all instruments must undergo Calibration.
- If physicochemical testing of product is performed as part of manufacturing steps, separate laboratory room may be waived and considered part of production process.
- Contract Testing with external laboratory is permitted.

B. Microbiological Laboratory:

Laboratory must be Controlled Area.

- It must have separate entrance and be internally divided into isolated zones with physical or spatial separation to prevent Cross Contamination, according to following laboratory activities:
  1. Washing Area.
  2. Preparation Area.
  3. Incubators Area – at least 2 incubators must be provided.
  4. Autoclave Area for Sterilization.
  5. Autoclave Area for Destruction (Decontamination Autoclave).
  6. Area containing Laminar Air Flow (LAF) unit.
- All instruments must undergo Calibration.
- Differential Pressure Gauges must be installed.
- Temperature and humidity monitors must be provided in laboratory.
- In case water is used, type and source of water must be specified.

» In case of Contract Testing with external laboratory meeting same requirements mentioned above, contracted laboratory must be subject to oversight by Egyptian Drug Authority (EDA) for tests performed there (including environmental control tests for cleanroom and microbiological tests on product). SOPs for sampling, handling, and transportation must be submitted. If factory violates this requirement during operation, actions will be taken in accordance with applicable rules and decisions, pursuant to Law No. 15 of 2017 and Law No. 151 of 2019.

Air Handling Unit (AHU) - HVAC System: Includes following:

- Pre-filter, Bag Filter (secondary), and High-Efficiency Particulate Air (HEPA) Filter.
- Installation of Differential Pressure Gauges across Pre-filter and Bag Filter, as well as before and after HEPA Filter.
- Placement of AHU in dedicated Technical Room or covered area; floors must be tiled and surrounding area kept clean.
- Conduct necessary Integrity Tests to ensure safety and proper functioning of AHU.

Sterilization (Performed by User):

- Valid and Approved Method of Sterilization provided by manufacturer must be included inside packaging.

B. Requirements for Factories Producing Orthopedic Surgical Devices and Surgical Instruments

Technical Requirements for Factory:

1. Restrooms—if present—must be separated from changing rooms, with restrooms located prior to Gowning Area.
2. Provision of open shoe racks; dedicated rack for street shoes and separate rack for restroom shoes (if applicable).
3. Provision of ventilation source in restrooms (if present).
4. Installation of air curtains and Electronic Insect Killers (EIK) at all factory entrances facing street directly.
5. Use of rust-proof stainless steel insect screens on all ventilation openings.
6. Separation of street shoes from internal factory footwear.
7. Separation of workers' outer clothing from factory-specific uniforms.
8. Provision of ventilation source.

Facilities and Infrastructure:

Warehouses

In case of single warehouse, space must be appropriate to nature of product and internally partitioned into separate zones with physical or spatial separation.
Warehouses are partitioned into following areas according to nature of final product and production components:

- Receiving Area.
- Raw Materials Storage Area.
- Packaging Materials Storage Area.
- Rejection Area for final product; must be secured and locked.
- Finished Product Storage Area.
- Special Storage Area for raw materials or products requiring specific storage conditions.

The following requirements apply:

1. Covered loading area must be provided to protect products or raw materials from sunlight or weather changes during transit.
2. Adequate ventilation must be available.
3. Temperature and humidity gauges must be installed, with conditions suitable for nature of product.
4. Floors must be durable (e.g., helicopter-finished concrete or epoxy).
5. Rodent control program must be in place.
6. All warehouse doors must be tightly closed to prevent entry of dust or insects.
7. Ventilation openings must be fitted with fine mesh wire, and glass treated (e.g., opaque/tinted) to prevent direct sunlight.
8. No direct water source shall exist in storage area.
9. Products must not be stored directly on floor; pallets or racks compliant with Good Storage Practices (GSP) and industrial safety must be used, maintaining clearance of 60 cm from ceiling soffit and 20 cm from walls.

Note: If separate warehouse for finished product exists, all above requirements must be fully implemented.

Production Areas

Gowning Area (Before Entering Production Zones – According to Product Manufacturing Specifications):

1. Unclassified Area (non-air-classified).
2. Workers must wear factory garments, hair cover, and shoe covers at minimum.
3. If changing clothing and shoes is required, Personnel Lockers must be provided to separate street attire from factory uniforms, sized appropriately for worker count.
4. Adequate ventilation must be provided.
5. Hand disinfectant must be available.
6. Walls and floors must be durable with smooth surfaces (Stout, Smooth).
7. Pictorial Standard Operating Procedures (SOPs) must be displayed for pre-entry procedures.

Production Area:

Products are produced within this area, which must comply with following requirements:

1. Unclassified Area (non-air-classified).
2. Area must be separate.
3. If water is used in production, its inlet and outlet paths to/from machines must be Closed Loop System.
4. Suitable ventilation system must be provided to maintain required temperature and humidity.
5. Temperature and humidity gauges must be installed, ensuring compliance with threshold limits and safety procedures according to product specifications and Material Safety Data Sheet (MSDS).
6. Floors must be durable, smooth, and clean.
7. Dedicated area for storing molds and dies must be provided, if required.

Polishing Area (Separate Zone):

1. Indirect ventilation (Well-Ventilated) must be provided; use of fans is prohibited..
2. Walls and floors must be durable, smooth, and clean.
3. Drain openings in sinks used for washing must be Sanitary Sinks.
4. Temperature and humidity gauges must be installed, complying with product-specific requirements, used equipment, and Material Safety Data Sheet (MSDS).

Laser Marking Stage: Stage in which data is printed on medical device

1. Indirect ventilation (Well-Ventilated) must be provided; use of fans is prohibited.
2. Walls and floors must be durable, smooth, and clean.
3. Temperature and humidity gauges must be installed, complying with product-specific requirements and Material Safety Data Sheet (MSDS).
4. No water source shall be present in this area.

Washing Area (Controlled Area): Area where medical devices are washed and dried before entering Cleanroom

1. Separate, unclassified area (Unclassified – non-air-classified).
2. Compressed air used for drying medical devices must be Oil & Water-Free.
3. Drain openings in sinks used for washing must be Sanitary Sinks.
4. Indirect ventilation (Well-Ventilated) must be provided; use of fans is prohibited.
5. Temperature and humidity gauges must be installed, ensuring compliance with product-specific requirements and Material Safety Data Sheet (MSDS).
6. Floors must be durable, smooth, and clean.
7. Supply and Return Air Grilles must be provided for proper ventilation.
8. When transferring products from Controlled Room to Cleanroom, following must be observed:
    a. Place product in double bags (Double Bagging) and transfer to Cleanroom via Classified Airlock or Dynamic Pass Box.
    b. Store product in intermediate warehouse compliant with Good Storage Practices (GSP).

Secondary Gowning Area (Before Entering Cleanroom): Area where workers change clothes before entering Cleanroom

- Workers change attire and pass over Step-over Bench before putting on cleanroom garments (Secondary Gowning).
- Doors must be Interlocked (synchronized closing).
- Area must be classified as ISO Class 8 / Class D.
- Pressure Cascading must be maintained by installing differential pressure gauges to ensure:
  Pressure differential between adjacent cleanrooms or clean zones of different cleanliness levels typically ranges from 5 Pa to 20 Pa, allowing doors to be opened safely and preventing unintended cross-flows due to turbulence.
- Pressure differential between adjacent rooms with different cleanliness levels must be between 5–20 Pa, allowing doors to open while preventing cross-contamination.
  i.e.: Between rooms of different grades, pressure differential should be approximately 10–15 ± 5 Pa.
- Air Grilles must not be office-type.
- Standard Operating Procedures (SOPs) must be displayed, detailing worker entry procedures into Cleanroom.

Cleanroom: Area in which final product is packaged

Pressure Cascading must be maintained by installing differential pressure gauges to ensure:

- Pressure differential between adjacent cleanrooms or clean zones of different cleanliness level should lie typically in range of 5 Pa to 20 Pa, to allow doors to be opened and to avoid unintended cross-flows due to turbulence.
- Pressure differential between adjacent rooms differing in cleanliness grades must be between 5–20 Pa, allowing doors to open and preventing cross-contamination.
- Between rooms of different grades, pressure differential should be approximately 10–15 ± 5 Pa.
- Doors must open toward cleaner direction, in direction of higher pressure (More Positive).
- Floors must be strong and smooth (e.g., epoxy or vinyl).
- Walls must be smooth; junction between walls and floors must be curved (Coving).
- Temperature and humidity gauges must be provided.
- Temperature and humidity must be controlled: 22 ± 2 °C and 65 ± 5% (supporting minimal bacterial growth unless other technical requirements apply).
- Supplies must enter through Aerated Pass Box or Classified Airlock.
- Differential Pressure Gauges must be installed at all doors and Dynamic Pass Boxes of Cleanroom.
- Supply Air Grilles must be provided in ceiling; Return Air Grilles must be provided in ceiling or side walls. If side-wall installed, they must be at suitable distance to allow proper air return.
- Air Grilles must not be office-type.
- Height between floor and ceiling must not be less than 2.60 m.
- Air Change Rate (ACR) must be between 15–20 air changes per hour, in accordance with ISO 14644.

Number of air changes range between 15-20/h.

Laboratories:

A. Physicochemical Laboratory:

- Laboratory must be located in separate room, with following considerations:
  - » Area must be suitable for personnel count and for type and volume of activity.
  - » Availability of suitable place for storing chemicals, ensuring storage in accordance with requirements stated on containers.
  - » Safety measures must be observed in laboratory.
  - » Laboratory must be equipped with necessary devices according to medical device; all devices must undergo Calibration.
- In case physicochemical testing of product is carried out through manufacturing steps, separate laboratory may be waived and considered part of production process.
- Contract Testing with external laboratory is permitted.

B. Microbiological Laboratory: Laboratory must be Controlled Area

- It must have separate entrance or be internally divided into isolated areas separated by spatial or physical barriers to prevent Cross Contamination, according to following laboratory activities:
  1. Washing Area.
  2. Preparation Area.
  3. Incubators Area; number of incubators must not be less than 2.
  4. Autoclave Area for Sterilization.
  5. Autoclave Area for Destruction (Decontamination Autoclave).
  6. Area containing Laminar Air Flow (LAF) unit.

- All instruments must undergo Calibration.
- Differential Pressure Gauges must be installed.
- Temperature and humidity monitoring instruments must be provided within laboratory.
- If water is used, type and source must be specified.

» In case of Contract Testing with external laboratory, it must comply with same requirements. Contracted laboratory must be subject to oversight by Egyptian Drug Authority (EDA) for performed tests, including environmental control of cleanrooms and microbiological testing of product, with submission of Standard Operating Procedures (SOPs) for sampling, handling, and transportation.

» If manufacturer fails to comply with these requirements during operation, actions will be taken in accordance with applicable regulations and decisions, pursuant to Law No. 15 of 2017 and Law No. 151 of 2019.

Water Treatment Plant (WTP):

- Water Treatment Plant must be established if product nature requires use of treated water, provided that plant complies with specifications.
- If water is supplied by external party (factory subject to oversight by Egyptian Drug Authority (EDA)), contract with supplier and water analysis certificates must be submitted.

Air Handling Unit - HVAC System: Includes following:

- Pre-filter, Bag Filter (secondary), and High-Efficiency Particulate Air (HEPA) Filter.
- Differential Pressure Gauges must be installed across Pre-filter and Bag Filter, as well as before and after HEPA Filter.
- Air Handling Unit (AHU) must be placed in dedicated Technical Room or covered by canopy; floors must be tiled and surrounding area kept clean.
- Necessary tests must be conducted to ensure integrity and safety of AHU.

Sterilization (Performed by User):

- Approved and Valid Method of Sterilization from manufacturer must be included inside packaging.

3. Licensing Requirements for Factories Producing Sterile Medical Devices (e.g., surgical implants, medical syringes, infusion sets, surgical drapes, and sterile medical garments)

Technical Requirements for Factory:

1. Restrooms must be separated from changing rooms, with restrooms located before Gowning Area.
2. Separate shoe racks must be provided: one for street shoes and another for restroom shoes (open type).
3. Ventilation source must be provided in restrooms.
4. Air curtains and Electronic Insect Killers (EIK) must be installed at all factory entrances facing street directly.
5. All ventilation openings must be fitted with fine mesh screens (rust-resistant).
6. Occupational health and safety requirements for workers must be observed.
7. Electric generator must be provided for operations or processes requiring Uninterrupted Power Supply (UPS).

Facilities and Infrastructure:

Factory Gowning Area:

This is area where street clothes are replaced with factory garments; it is Unclassified. Following must be observed:

1. Separation of street shoes from internal factory footwear.
2. Separation of workers' outer clothing from factory uniforms.
3. Provision of ventilation source.
4. Exhaust Fan must be provided.

Warehouses

Warehouses are divided into following areas (according to nature of final product and production components):

- Receiving Area.
- Raw Materials Storage Area.
- Packaging and Labeling Materials Storage Area.
- Sampling Area (classified same as production area when powders are used as raw materials) or Inspection Area under controlled environmental conditions.
- Weighing Area (classified as ISO 8 / Class D when powders are used as raw materials).
- Rejection Area for final products; must be tightly sealed and Secured.
- Finished Product Storage Area.
- Storage area for raw materials or products requiring Special Storage Conditions.

The following requirements apply:

1. If single warehouse exists, space must be appropriate for product type and internally partitioned into isolated areas via spatial or physical barriers.
2. Covered area must be provided to ensure products or raw materials are not exposed to sunlight or weather changes during loading/unloading.
3. Receiving Area must meet the following:
    - Equipped with two doors using Interlocked system.

- Fitted with air curtains and insect traps.
- Ventilation must be consistent with rest of warehouse.

4. Good ventilation must be provided.
5. Temperature and humidity measuring devices must be available.
6. Temperature and humidity levels must be appropriate for nature of product.
7. Floors must be durable (e.g., helicopter-finished concrete).
8. Rodent control system must be in place.
9. All warehouse doors must be tightly sealed to prevent entry of dust or insects.
10. Ventilation openings must be fitted with fine mesh screens, and glass treated (e.g., opaque/tinted) to prevent direct sunlight.
11. Adequate lighting must be provided.
12. No direct water sources shall exist in storage area.
13. Storage on floor is prohibited; pallets or racks complying with Good Storage Practices (GSP) and industrial safety must be used. Storage must maintain clearance of 60 cm from ceiling soffit and 20 cm from walls.

Note: If separate warehouse for finished product exists, all above requirements must be fully implemented.

Production Areas

Control Gowning Area:

1. Unclassified Area (non-air-classified).
2. Lockers for garments and shoes must be provided, appropriate for personnel count, along with Step-over Bench (coated metal or stainless steel).
3. Dedicated Gowning Areas must be designated for females and males.
4. Shoes must be changed to area-specific footwear.
5. Workers' outer clothing must be separated from area-specific garments.
6. Ventilation source must be provided.
7. Handwashing sinks are prohibited; hand disinfectant must be provided.
8. Walls and floors must be durable, smooth, and seamless (Stout, smooth, with no joints).
9. Indirect ventilation (no fans) and adequate, covered lighting must be provided.

Controlled Room:

Area where primary components or intermediate products are produced, provided they do not support bacterial growth.

1. Unclassified Area (non-air-classified).
2. Controlled Room must be separate and not used as a passageway.
3. If water is used in production, entry and exit paths to/from equipment must be Closed Loop System.
4. Dedicated area must be provided for cleaning and removing external packaging of raw materials before entry to Controlled Room. This area must have ventilation source and Exhaust Fan.
5. Indirect ventilation must be provided; use of fans is prohibited.
6. Temperature and humidity measuring devices must be available inside Controlled Room, with levels maintained according to product specifications and Material Safety Data Sheet (MSDS).
7. Floors must be durable, smooth, and clean (e.g., tile or epoxy).
8. Supply and Return Air Grilles must be provided.
9. Dedicated area for storing molds must be attached to Controlled Room, if required.
10. When transferring product from Controlled Room to Cleanroom:
    a. Product must be placed in Double Bagging and transferred via Classified Airlock or Dynamic Pass Box.
    b. Product must be stored in intermediate warehouse compliant with Good Storage Practices (GSP).

Secondary Gowning Area:

Area where clothing is changed before entering Cleanroom.

- Personnel change attire and pass over Step-over Bench to don cleanroom garments (Secondary Gowning).
- Doors must be Interlocked.
- Area classification must be no less than ISO Class 8 / Class D. Pressure Cascading must be ensured if production occurs in area classified higher than ISO Class 8 / Class D.
- Pressure Cascading must be maintained using differential pressure gauges:
  Pressure differential between adjacent cleanrooms or clean zones of different cleanliness level should lie typically in range of 5 Pa to 20 Pa, to allow doors to be opened and to avoid unintended cross-flows due to turbulence.
- Pressure differential between adjacent rooms with different cleanliness levels must range between 5–20 Pa.
  i.e.: Between rooms of different grades, pressure differential should be approximately 10–15 ± 5 Pa.
- Air Grilles must not be office-type.

Cleanroom:

Area where production, assembly, printing, and packaging take place.

- Area must be air-classified at minimum ISO Class 8 / Class D.
- It must be preceded by Secondary Gowning area (Step-over Bench and cleanroom garments).
- Doors must be Interlocked.
- Gowning Area preceding clean area must have same air classification as Cleanroom.
- Pressure Cascading must be maintained using differential pressure gauges:
  Pressure differential between adjacent cleanrooms or clean zones of different cleanliness level should lie typically in range of 5 Pa to 20 Pa, to allow doors to be opened and to avoid unintended cross-flows due to turbulence.
- Pressure differential between adjacent rooms with different cleanliness classifications must range between 5–20 Pa.
  i.e.: Between rooms of different grades, pressure differential should be approximately 10–15 ± 5 Pa.
- Doors must open toward cleaner area (direction of higher positive pressure).
- Floors must be durable and smooth (e.g., epoxy or vinyl).
- Walls must be smooth; junction between walls and floors must be curved (Coving).
- Temperature and humidity measuring devices must be provided.
- Temperature must not exceed 22 ± 2 °C and humidity 65 ± 5% (to minimize bacterial growth).
- Printing on product must be performed inside Cleanroom. If inks are used, ink handling area must have Physical Separation.
- If printing is performed outside Cleanroom, Justification must be provided.
- Raw materials must enter through Aerated/Dynamic Pass Box or Classified Airlock.
- Differential Pressure Gauges must be installed at all doors and Dynamic Pass Boxes of Cleanroom.
- Supply Air Grilles must be in ceiling; Return Air Grilles in ceiling or side walls (at suitable distance for proper air return).
- Air Grilles must not be office-type.
- Height between floor and ceiling must not be less than 2.60 m.
- Air Change Rate (ACR) must be 15–20 changes per hour per ISO 14644.

Laboratories:

A. Physicochemical Laboratory:

- Laboratory must be located in separate room, taking into consideration following:
  - » Area must be suitable for personnel count, type of activity, and its scale.
  - » Suitable area must be provided for storage of chemicals, in accordance with storage requirements indicated on containers.
  - » Safety measures must be observed within laboratory.
  - » Laboratory must be equipped with necessary instruments according to medical device requirements; all instruments must undergo Calibration
- If physicochemical testing is performed during manufacturing steps, separate laboratory room may be waived and testing considered part of production process.
- Contract Testing with external laboratory is permitted.

B. Microbiological Laboratory: Laboratory must be Controlled Area

- It must have separate entrance or be internally divided into isolated areas with spatial or physical barriers to prevent Cross-contamination, according to following laboratory activities:
  1. Washing Area.
  2. Preparation Area.
  3. Incubators Area, with minimum of 2 incubators.
  4. Autoclave Area for Sterilization (Sterilization Autoclave).
  5. Autoclave Area for Destruction (Decontamination Autoclave).
  6. Room containing Laminar Air Flow (LAF) unit with following specifications:
     - Surrounding area must be air-classified according to production room classification, with minimum of ISO Class 8 / Class D.
     - It must be preceded by Airlock for gowning, classified as ISO Class 8 / Class D.
     - Floor must be covered with smooth material (e.g., epoxy) with no joints; junction between walls and floors must be curved (Coving).
     - Dynamic Pass Box must be provided in LAF room.
- All instruments must undergo Calibration.
- Differential Pressure Gauges must be provided.
- Temperature and humidity measuring devices must be available in laboratory.
- If water is used, its type and source must be specified.

» If external laboratory is contracted, it must comply with same requirements. Contracted laboratory must be subject to oversight by Egyptian Drug Authority (EDA) for performed tests (environmental control of cleanrooms and microbiological testing of products), with submission of SOPs for sampling, handling, and transportation.

» If manufacturer violates this condition during operation, actions shall be taken in accordance with applicable regulations and decisions, pursuant to Law No. 15 of 2017 and Law No. 151 of 2019.

Water Treatment Station (WTS):

- Water Treatment Station must be established if manufacturing of medical device requires or uses treated water. Water Treatment Station consists of following components:
  a. City water tank (made from Stainless Steel Grade 316L, Polyethylene, or Polypropylene).
  b. Sand filter.
  c. Carbon filter (activated granular carbon); at least one filter.
  d. Two (duplex) water softeners.
  e. Storage tank for soft water.
  f. Reverse Osmosis (RO), Ion Exchange Resin, or Electrodialysis (for water purification).
  g. UV Lamp.
  h. Bacterial filter (0.2 micron).
  i. Stainless steel tank for storage of Purified Water (Storage conditions: above 85°C or below 25°C).

The following requirements must be observed at Water Treatment Station:

- Water specifications must be appropriate for type of medical device to be licensed.
- All rust-causing metals (iron, aluminum, copper) must be excluded.
- Spray ball and vent filter must be installed in Purified Water storage tank.
- Dead legs must be avoided to prevent contamination.
- Continuous water circulation must be maintained to prevent stagnancy.
- Daily water monitoring must be conducted at multiple designated sampling points.
- All storage tanks must be identified, and water flow direction must be labeled.
- If water is supplied by external source (factory subject to oversight by Egyptian Drug Authority (EDA)), supply contract and water analysis certificates must be submitted.

Air Handling Unit (AHU) - HVAC System:

This system includes the following:

- Pre-filter, secondary filter (Bag Filter), and High-Efficiency Particulate Air (HEPA) filter.
- Differential Pressure Gauges must be installed at Bag Filter and Pre-filter, as well as before and after HEPA filter.
- Air Handling Unit (AHU) must be installed in dedicated Technical Room or covered with canopy; floors must be tiled and surrounding area kept clean.
- Necessary tests must be performed to ensure integrity and safety of AHU.

Sterilization:

If sterilization methods other than those listed below are used, each case is studied individually.

A. Gamma Radiation Sterilization:

- Medical Device Inspection Department ensures existence of contract between manufacturer and Atomic Energy Authority.

B. Steam Sterilization

- Valid calibration certificate must be available.
- Validation studies are monitored by Medical Device Inspection Department.
- If water treatment station is used, its specific requirements must be followed.
- If manufacturer does not have a water treatment station, Water Softener must be used at water inlet of Sterilization Autoclave.

C. Gas Sterilization (e.g., Ethylene Oxide / Nitrogen Dioxide):

- Acceptance certificates from equipment manufacturer (Acceptance Test), Installation Qualification (IQ), and Operational Qualification (OQ) must be available.
- Sterilization must be conducted in separate room equipped with exhaust systems.
- Secure storage area must be provided for gas cylinders; empty and full cylinders must be stored separately.
- Pallets suitable for equipment must be used in accordance with manufacturer's operating instructions.

Aeration Room:

a. Room must be of sufficient size to accommodate sterilization loads, taking into account maximum number of sterilization cycles during 48-hour incubation period of Biological Indicator (BI).
b. Temperature and humidity measuring devices must be provided.
c. Heater must be available if required.
    - If manufacturer designates Pre-conditioning Area, Thermal Mapping must be submitted.
    - Aeration area may be omitted if it is proven that sterilization unit is capable of performing sufficient washing (pulsing) to reach acceptable Residual Ethylene Oxide levels. Storage volume must be sufficient to retain loads for 48 hours until microbiological test results of Biological Indicator are available.

Note:

If manufacturer does not implement any of above requirements due to nature of medical device manufacturing process, manufacturer must provide studies supported with Justification and Reference. These studies shall be submitted to competent committee for factory licensing (IDA's joint committee and Egyptian Drug Authority (EDA)) during inspection.

4. Licensing Requirements for Manufacturing of Laboratory and Diagnostic Reagents in accordance with IVDR (In Vitro Diagnostic Regulation)

Production areas shall be classified according to microbiological status of final product, risk assessment submitted by industrial establishment, and manufacturing specifications (if available).

General Site Requirements:

1. Generator must be provided and connected to factory electrical circuit in case of specific requirements for product manufacturing or storage.
2. Equipment operating on mains electricity versus generator must be clearly identified in engineering diagram.

Facilities and Utilities

Personnel Entry Area

1. Restrooms must be separated from Gowning Area, with restrooms located before gowning entry.
2. Shoe racks (open stands) must be provided: one for street shoes and another for factory footwear.
3. Ventilation source must be provided in restrooms.
4. Air curtains and Electronic Insect Killers (EIK) must be installed at all factory entrances facing street.

Gowning Area: Unclassified area where street clothes are exchanged for factory garments.

1. Separation of street shoes from factory-specific footwear.
2. Separation of workers' outer garments from factory clothing.
3. Ventilation source and Exhaust Fan must be provided.
4. Lockers and Step-over Bench must be made of coated metal or stainless steel.
5. Dedicated Gowning Areas must be provided for personnel.
6. Separate lockers must be provided for street clothes and factory clothes.
7. No water sources shall be present in Gowning Area.
8. Hand disinfectant must be provided.
9. Walls and floors must be durable with smooth surfaces. Expansion joints must be treated according to industrial standards to prevent dust accumulation and maintain surface smoothness.
10. Ventilation must be adequate.
11. Lighting must be sufficient and protected/covered.
12. All ventilation openings must be covered with fine, rust-resistant mesh.

Warehouses

Warehouses are divided according to the nature of final product and production components:

- Raw material storage area.
- Packaging and labeling material storage area.
- Rejected final product area (securely closed and locked).
- Finished product storage area.
- Storage area for materials requiring special conditions.

Warehouse Requirements:

1. Well-ventilated storage.
2. Covered loading area to protect materials from sunlight or weather changes.
3. Adherence to specific storage requirements for products/raw materials.
4. Temperature and humidity measuring devices must be provided.
5. Floors must be durable.
6. Pest control system must be implemented.
7. Doors must be tightly closed to prevent dust/insects.
8. Fine mesh on ventilation openings and treated/opaque glass to prevent direct sunlight.
9. Adequate lighting.
10. No water sources in storage area.
11. Storage on floor is prohibited; Pallets or stands compliant with Good Storage Practices (GSP) must be used. Clearance: 60 cm from ceiling and 20 cm from walls.
12. If refrigerator is required: a. Equipped with calibrated temperature gauges. b. Temperature readings must be recorded regularly.

Production Areas

Controlled Room:

It is an area for production and packaging of products not requiring Cleanroom environment.

1. Must be separate and not used as passageway.
2. Appropriate ventilation system must be provided.
3. Temperature should preferably not exceed 22 ± 2°C and humidity 65 ± 5%, unless specific requirements dictate otherwise.
4. For reagents requiring reduced humidity, Dehumidifier or other engineering solutions must be provided.
5. Temperature and humidity must meet Material Safety Data Sheet (MSDS) or product specifications.
6. All gauges affecting product safety must undergo Calibration.
7. Floors must be smooth, clean, and durable.
8. Dedicated area attached to Controlled Room for storing molds or tools.
9. Production stage must be separated from packaging stage.

Secondary Gowning Area

It is an area for changing clothes before entering Cleanroom.

1. Standard Operating Procedures (SOPs) must be displayed defining procedures for entering Cleanroom.
2. Personnel change clothes, pass over Step-over Bench, and don cleanroom garments (Secondary Gowning).
3. Doors must be Interlocked.
4. Classification at least ISO Class 8 / Class D. Pressure Cascading must be verified.

5. Pressure Cascading must be maintained using differential pressure gauges:
   Pressure differential between adjacent cleanrooms or clean zones of different cleanliness level should lie typically in range of 5 Pa to 20 Pa.
- Differential pressure between rooms of different grades should be approximately 10–15 Pa ± 5.
- Air Grilles must not be standard commercial/office type.

Cleanroom: Area for production and packaging of products requiring Classified Cleanroom environment

- Preceded by Secondary Gowning Area with same air classification.
- Calibrated differential pressure gauges must be installed.
- Pressure Cascading must be observed:
  Pressure differential between adjacent rooms with different cleanliness levels shall be between 5–20 Pa.
- Doors must open toward area of higher air pressure (More Positive).
- Floors and walls must be smooth; junctions (wall-to-ceiling or wall-to-floor) must be curved (Coving).
- Calibrated instruments for temperature and humidity.
- Preferably, temperature ≤ 22 ± 2°C and humidity ≤ 65 ± 5%.
- Printing on product must occur inside Cleanroom; if inks are used, Physical Separation is required.
- Raw materials must be introduced via Dynamic Pass Box or Classified Airlock.
- Supply Air Grilles in ceiling; Return Air Grilles in ceiling or side walls (at appropriate distance).
- Height from floor to ceiling must be at least 2.6 m.
- Air Change Rate (ACR) must comply with class (e.g., ISO Class 8 / Class D: 15–20 changes per hour).
- Production stage must be separated from packaging/filling stage.

Laboratories:

1. Product-specific testing requirements must be met. For instance, if products require microbiological analysis, Microbiology Laboratory must be provided, fully equipped with necessary instruments to perform required tests.
2. If in-house Quality Control (QC) or Microbiology Laboratory is unavailable, manufacturer must contract with pre-licensed external laboratory. External laboratory shall be inspected to ensure all requirements for testing factory products are met.
3. Contract must include clause allowing inspection of laboratory regarding analysis of contracted products; laboratory is required to provide Records.
4. All equipment necessary for testing must be available according to product requirements.
5. Calibration requirements of relevant Standard must be met for all laboratory equipment.
6. Labelling must be applied to equipment indicating calibration status, validity, and next calibration date.

Material Control:

1. Approved Supplier List (ASL) must be maintained.
2. Supplier Selection Checklist must be established.
3. Selection criteria must include Quality, Safety, and Performance requirements.

Cleanroom Specifications:

- Floors and walls must be smooth; wall-to-floor or wall-to-ceiling junctions must be curved (Coving).
- Calibrated temperature and humidity gauges must be installed.
- Preferred conditions: temperature 22 ± 2°C and humidity 65 ± 5%, unless product-specific requirements dictate otherwise.
- If printing is performed on product, it must occur inside Cleanroom. If inks are used, Physical Separation must be maintained. Materials must be introduced through Dynamic Pass Box or Classified Airlock.
- Supply Air Grilles must be installed on ceiling; Return Air Grilles on ceiling or side walls. Side wall return grilles must be positioned at appropriate distance for proper air retrieval.
- Floor-to-ceiling height must not be less than 2.6 meters.
- Air Change Rate (ACR) must comply with room classification (e.g., ISO Class 8 / Class D: 15–20 changes per hour per ISO 14644).
- Production and packaging/filling processes must be physically separated.

Water Systems:

- If water is used in manufacturing, factory must have water station meeting requirements for producing water in compliance with technical specifications stated in product specification, or laboratory-use water specifications in latest editions of ASTM International.
- In case of Outsourcing of Water, factory must comply with requirements in Material Control clause.
- Water station may consist of compact Reverse Osmosis (RO) units without softeners upstream for small quantities (up to 100 liters/day). If factory requires quantities exceeding this amount, comprehensive water treatment station must be provided, including:
    1. Sand Filter.
    2. Micron Filters.
    3. Softener.
    4. Carbon Filter or sodium metabisulfite injection system.
    5. RO unit, followed by additional RO stage if required by specifications.
- If water is used directly without storage, small RO units or water treatment station may be utilized according to production requirements.
- If water storage is required, it must be through Closed-loop System; both inlet and outlet must be within loop.
- Factory must conduct and document water testing to ensure compliance with requirements.

Air Handling Unit (AHU) - HVAC System:

- Air Handling Unit (AHU) must include: Pre-filter, Bag Filter, and HEPA Filter.
- Differential Pressure Gauges must be installed to measure pressure drop across Pre-filter and Bag Filter, and before/after HEPA Filter.
- AHU must be covered with canopy; floors must be tiled and surrounding area kept clean.
- Necessary tests must be performed to verify integrity of AHU and compliance with specifications.

Note:

If factory does not apply any of above requirements due to nature of manufacturing laboratory/diagnostic reagents, factory must submit studies supported by Justification and Reference to competent committee responsible for factory licensing.

5. Licensing Requirements for Factories Producing Prosthetic Limbs, Orthotic Devices, and Mobility Aids

These requirements apply to manufacture of prosthetic limbs, orthotic devices, and mobility aids classified as:

- Class I: (Non-sterile, non-measurable) under medical device regulations.
- Class I: (FDA Sec 890.3025).

Definitions

Term	Technical Definition
Orthosis / Orthotic Device	Externally applied device used to modify structural and functional characteristics of neuromuscular and skeletal systems.
Orthotics	Science and art of treating people through use of orthoses.
Orthotist	Person who has completed approved course of education and training and is authorized by appropriate national authority to design, measure, and fit orthoses.
Mobility Aids	Devices such as walking sticks, crutches, walkers, and wheelchairs.
Prosthesis / Prosthetic Device	Externally applied device used to replace wholly or partly an absent or deficient limb segment.
Prosthetics	Science and art of treating people through use of prostheses.
Prosthetist	Person authorized by appropriate national authority to design, measure, and fit prostheses.
Prosthetist and Orthotist (P&O)	Person who has completed approved course of education and training and is authorized by appropriate national authority to design, measure, and fit prostheses and orthoses.
Custom-made Device	Device specifically made in accordance with written prescription from authorized professional; features specific design characteristics intended for sole use of particular patient to meet individual needs. I
Manufacturing Facilities	Facilities manufacturing components of prosthetic limbs, orthotic devices, and mobility aids without direct patient interaction.
Assembly and Fitting Facilities	Facilities purchasing prosthetic components and fabricating patient-specific parts (e.g., Sockets) and assembling devices for individual patients.
Category I: Full professional Prosthetist / Orthotist	Full professional Prosthetist / Orthotist.
Category II: Orthopedic or Prosthetist Technologist	Orthopedic or Prosthetist Technologist.
Category III: Bench Worker	Bench Worker; needed to support Category I and II personnel but not considered service providers.

Requirements consist of 3 Axes, applied according to activity type (Manufacturing or Assembly/ Fitting):

- **First Axis:** Requirements for personnel and technical facility standards.
- **Second Axis:** Control of production inputs and components.
- **Third Axis:** Machinery and equipment.

Requirements for Manufacturing Facilities:

(1) Requirements for Personnel:

Adherence to same requirements for medical device factories per International Standard: ISO 13485:2016 – Quality Management System (QMS).

- Personnel performing work affecting product quality must be competent based on appropriate education, training, skills, and experience.
- Facility must document process for establishing competence, providing needed training, and ensuring awareness of personnel.
- Facility must:
  a. Determine necessary competence for personnel performing work affecting product quality.
  b. Provide training or take other actions to achieve or maintain necessary competence.
  c. Evaluate effectiveness of actions taken.
  d. Ensure personnel are aware of relevance and importance of their activities and how they contribute to achievement of Quality Objectives.
  e. Maintain appropriate records of education, training, skills, and experience.

Note: Methodology used to check effectiveness is proportionate to risk associated with work for which training or other action is being provided.

(2) Facility Technical Requirements:

Requirements are categorized into Mandatory Requirements and Non-mandatory Rules. Factory must achieve 50% compliance with Non-mandatory Rules to satisfy licensing criteria, effectively elevating selected non-mandatory provisions to mandatory status as detailed below:

Mandatory Requirements	Non-mandatory Rules
Separation of restrooms from changing rooms; restrooms must be located before Gowning Area.	Provision of shoe racks (open stands) for street shoes and separate racks for restroom footwear.
Provision of ventilation source in restrooms.	
Installation of air curtains and Electronic Insect Killers (EIK) at all factory entrances (directly fronting street).	

Facilities and Infrastructure:

Storage Areas:

Storage areas are divided into following zones (according to nature of final product; applied based on activity need, size, and production components):

- Receiving Area.
- Raw material storage area.
- Packaging and labeling material storage area.
- Rejection Area (must be securely closed and Secured).
- Semi-Finished Product Storage Area (if necessitated by manufacturing process).
- Finished product storage area.
- Special Storage Area (for raw materials or products requiring special storage conditions, e.g., chemicals and hazardous materials), subject to approval by licensing authority.

Following requirements must be observed in storage areas:

1. Provision of covered area (canopy) to ensure products or raw materials are not exposed to sunlight or weather changes during loading/unloading.
2. Receiving Area must meet following specifications:
    - Equipped with air curtains and Electronic Insect Killers (EIK).
    - Ventilation consistent with rest of storage area.
3. Temperature and humidity must be appropriate for product nature; periodic recording of temperature and humidity is mandatory.
4. Floors must be suitable for product nature.
5. All storage doors must be tightly sealed to prevent entry of dust or insects.
6. Fine mesh must be installed on any ventilation openings; glass must be treated (Opaque/ Frosted) to prevent direct sunlight.
7. Adequate lighting must be provided.
8. No direct water source in storage area.
9. Direct storage on floor is prohibited; non-flammable pallets or stands must be used. Storage must maintain clearance of 60 cm from ceiling and 20 cm from walls.

If separate warehouse for finished products exists, all aforementioned requirements must be met.

Production Areas

Production areas must adhere to following standards based on product nature:

- Non-sterile medical products intended for non-sterile use: Production and packaging within classified area is not required unless mandated by manufacturing specifications.
- Special conditions must be observed if necessitated by any manufacturing stage or production components.
- Manufacturing within controlled area is not required unless dictated by product nature.

Gowning Area (Primary):

Unclassified area used for exchanging street clothes for factory garments.

Mandatory Requirements	Non-mandatory Rules
Separation of street shoes from footwear worn inside factory.	Allocation of lockers for street clothes and separate lockers for factory garments.
Provision of adequate ventilation and lighting; area must be covered.	Absence of handwashing sinks in proximity to production areas; provision of disinfectant for hand hygiene.
Provision of step-over bench and lockers made of coated metal.	
Walls and floors must be stout, smooth, and without visible joints.	
Installation of fine mesh (rust-resistant) on all ventilation apertures.	
Allocation of separate Gowning Area for females and males (if applicable).	

Controlled Room (if necessitated by product nature):

It is the area designated for product preparation and packaging. The following requirements must be observed:

1. Controlled Room must be separate and not utilized as a corridor.
2. If water is utilized in production process, entry and exit must follow a closed-loop system.
3. Allocation of Gowning Area for changing clothes prior to entry.
4. Allocation of area for cleaning and removing outer packaging of raw materials before entry into Controlled Room; area must be equipped with ventilation and Exhaust Fan.
5. Provision of indirect well-ventilated source (direct fans are prohibited). Temperature must not exceed 30°C and humidity must not exceed 65%, with mandatory installation of monitoring devices.
6. Floors must be stout, smooth, and clean.
7. Allocation of area for mold storage attached to Controlled Room if required.

If factory performs packaging in a separate area, all aforementioned requirements must be fully implemented.

Clean Room (if necessitated by product nature):

If manufacturing specifications or Risk Assessment Study require production within clean room, requirements for licensing medical device factories shall apply. Same rules apply to Heating, Ventilation, and Air Conditioning (HVAC) System..

Laboratories:

Laboratory requirements are determined according to type of medical device produced and applicable standard:

1. Documented Documentation System must be in place, detailing analysis methods and release criteria to ensure product safety, along with post-market surveillance system in accordance with ISO 13485.
2. Product release documentation system must include checklist containing product specifications. Recipient uses this checklist to verify that device meets intended use, ensuring usability.
3. Record of all equipment used by factory must be maintained.
4. Compliance with Egyptian Drug Authority (EDA) Decision No. 499 of 2021 regarding use of international barcodes for all medical devices circulated in local market, including updates.
5. Compliance with EDA Decision No. 642 of 2021 concerning labeling information for medical and laboratory devices, diagnostic reagents, and production components/inputs, including updates.

For microbiology laboratories: If nature of product requires manufacturing in controlled environmental conditions, requirements for licensing medical device factories must be followed.

Control of Production Inputs and Components:

Current procedures must be followed, including maintaining approved raw material supplier list under Quality Management System (QMS), approved by factory. This involves reviewing supplier certifications, Certificates of Analysis (COA), and Safety Data Sheets (SDS) for imported raw materials, in accordance with Egyptian Drug Authority (EDA) protocols.

Machinery and Equipment:

Suitability of machinery for production process shall be reviewed by joint inspection committee formed by IDA and EDA, pursuant to licensing inspections under Law No. 15 of 2017 and Law No. 151 of 2019.

Note:

- If factory does not implement any aforementioned requirements due to nature of medical device, it must submit study supported by justifications and references to competent committee for factory licensing.
- Factory must submit Product List to EDA when applying for license, detailing devices to be manufactured and required manufacturing standards.
- All factories must comply with Guideline for Labeling Information for medical and laboratory devices, diagnostic reagents, and production components/inputs.

Fifth Product Guideline

Classification of Medical Device Manufacturing Factories:

Classification shall follow attached product guideline based on licensed products. Each new medical device shall be evaluated individually according to guideline.

References:

1. ISO 14644:2015: Cleanrooms and associated controlled environments.
2. ISO 11135:2014: Sterilization of health-care products — Ethylene oxide — Requirements for development, validation and routine control of sterilization process for medical devices.
3. ISO 13485:2016: Medical devices — Quality management systems — Requirements for regulatory purposes.
4. ISO 17025:2017: General requirements for competence of testing and calibration laboratories.
5. ISO 11607: Packaging for terminally sterilized medical devices.
6. IVDR: EU In Vitro Diagnostic Regulation.
7. MDR: EU Medical Device Regulation.
8. WHO standards for prosthetics & orthotics (Part 1: Standards).
9. European Union Medical Device Regulation — MDR.
10. WHO (Guidelines for training personnel in developing countries for prosthetics and orthotics services — World Health Organization 2005).
11. ISO 13485:2016 Medical devices — Quality Management System (QMS).
12. ISO 14971:2019 Application of risk management to medical devices.
13. ISO 14644:2015 Cleanrooms and associated controlled environments.
14. Al-Koud al-Masri li-Tasmim al-Faraghat al-Kharijiyya wal-Mabani li-Istikhdam al-Mu'aqin Koud Raqam 106 (Egyptian Code for Design of External Spaces and Buildings for Use of Disabled Persons — Code No. 106).
15. Al-Dalil al-Istrishadi al-Khass bi-Bayanat al-Mulsatqat lil-Mustalzamat wal-Ajhiza al-Tibbiyya wal-Ma'maliyya wal-Kawashif al-Tashkhisiyya wa-Mukawwinat wa-Midkhalat al-Intaj (Guideline for Labeling Information of Medical and Laboratory Devices, Diagnostic Reagents, and Production Components/Inputs).
16. Qarar A.D./Ra'is al-Hay'a Raqam 499 li-Sanat 2021 (Chairman of Authority Decision No. 499 of 2021).
17. Qarar A.D. Ra'is Hay'at al-Dawa' al-Masriyya Raqam 642 li-Sanat 2021 (Chairman of Egyptian Drug Authority (EDA) Decision No. 642 of 2021).
18. Qanun Insha' Hay'at al-Dawa' al-Masriyya Raqam 151 li-Sanat 2019 (Law Establishing Egyptian Drug Authority No. 151 of 2019).
19. MDD: 93/42/EEC.
20. Al-Dalil al-Irshadi al-Khass bi-Istirad al-Mustalzamat al-Tibbiyya bi-Kulli Anwa'iha (Guideline for Import of Medical Supplies of All Types).
21. Al-Dalil al-Irshadi al-Khass bi-Istikhdam al-Barkoud al-Duwali (Guideline for Use of International Barcode).