Technical Requirements for Licensing and Operating- Prosthetic, Orthotics, And Mobility Aid Factories 2026

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Guide Contents

First: Scope

These requirements apply to any entity that manufactures or assembles prosthetics, orthotics, and mobility aids

Second: Definitions

Orthosis, orthotic device or product: **Externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal systems**	**جهاز تقويمي:** **جهاز يستخدم خارجيًا لتعديل الخصائص الهيكلية والوظيفية للأنظمة العصبية والعضلية والهيكلية.**
Orthotics: **Science and art of treating people using orthoses**	**علم تقويم العظام:** **علم علاج الأشخاص باستخدام اجهزة التقويم.**
Orthotist: **A person who has completed an approved course of education and training and is authorized by an appropriate national authority to design, measure and fit orthoses**	**متخصص في الأجهزة التقويمية:** **الشخص المختص والمؤهل دراسيا وتدريبيا ومصرح له من قبل السلطة الوطنية المختصة لتصميم أجهزة تقويم العظام وقياسها والتأكد من مطابقتها.**
Walking Aids For example: walking sticks, crutches, walker, wheelchair, etc.	**مساعدات الحركة**
Prosthesis, prosthetic device or product: **Externally applied device used to replace wholly or partly an absent or deficient limb segment**	**الطرف الصناعي أو الجهاز الصناعي: جهاز يستخدم خارجيًا لاستبدال جزء مبتور أو غير موجود من الأطراف كلياً أو جزئياً.**
Prosthetics: **Science and art of treating people using prostheses**	**علم الأطراف الصناعية:** **العلم المسؤول عن علاج الناس باستخدام الطرف الصناعي.**

Prosthetist Person **Person who has completed an approved course of education and training and is authorized by an appropriate national authority to design, measure and fit prostheses**	**متخصص في الأطراف الصناعية:** **الشخص المختص والمؤهل دراسيا وتدريبيا ومصرح له من قبل السلطة الوطنية المختصة لتصميم وقياس وتركيب الأطراف الصناعية.**
Prosthetist and orthotist (P&O): **Person who has completed an approved course of education and training is authorized by an appropriate national authority to design, measure and fit prostheses and orthoses.**	**متخصص الأطراف الصناعية والأجهزة التقويمية:** **الشخص المختص والمؤهل دراسياً وتدريبية ومصرح له من قبل السلطة الوطنية المختصة لتصميم وقياس وتركيب الأطراف الصناعية والأجهزة التقويمية.**

'custom-made device': **as any device that: - is specifically made in accordance with a written prescription of any person authorized by national law by virtue of that person's professional qualifications; which gives - specific design characteristics provided under that person's responsibility; and - is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.**	**الجهاز المصمم حسب الطلب:** **جهاز يتم تصميمه بمواصفات معينة عن طريق المختص المؤهل بموجب القانون الوطني بموجب المؤهلات المهنية لذلك الشخص الذي يعطي خصائص تصميم محددة يتم توفيرها تحت مسؤولية ذلك الشخص ومخصص لاستخدام مريض معين حصرياً لتلبية ظروفه واحتياجاته الفردية.**
Production Factories: **Factories that manufacture prosthetic parts, orthotic devices, and mobility aids do not deal with a patient.**	**مصانع الإنتاج:** **المصانع التي ستقوم بتصنيع أجزاء الطرف الصناعي الأجهزة التقويمية ومساعدات الحركة ولا تتعامل مع مريض.**
Assembly and alignment Factories: **Factories that purchase prosthetic components, manufacture some orthotic devices and mobility aids specifically for each patient (custom made), and assemble and manufacture patient-specific parts such as sockets.**	**مصانع التجميع والمواءمة:** **المصانع التي ستقوم بشراء أجزاء الطرف الصناعي، وتصنع بعض من الأجهزة التقويمية ومساعدات الحركة خصيصاً لكل مريض وتجميعها وتصنيع الأجزاء الخاصة بالمريض مثل Socket**

Category 1: **Full professional prosthetist/orthotist**	**تم التصنيف طبقاً ل ISPO وتحديثاته.**
Category II: **orthopedic or Prosthetist technologist**	**تم التصنيف طبقا ل ISPO وتحديثاته.**
Category III: Bench worker, needed to support Category I and II personnel but are not considered as service providers	**تم التصنيف طبقاً ل ISPO وتحديثاته.**

Third: Classification of Medical devices

According to the European medical device's directive "EU-MDD-Annex VII:
A) Class I-Is (sterile) -Im (measurable), I (non-sterile)
b) class II a
c) class II b
d) class III
According to the US Food and Drug Administration FDA:
A) Class I
b) class II
c) class III
These requirements pertain to the manufacture of prosthetics, orthotics, and mobility aids, which are classified according to the medical devices' directive such as (class I(non-sterile ,non-measurable) or to FDA sec 890.3025:class I

Fourth: General Requirements

The general requirements apply to production factories and assembly and alignment centers as follows:
1-The factory must have obtained the necessary approvals and licenses from the competent authorities (Industrial Development Authority, Investment Authority, or Suez Canal Economic Zone)
2-The necessary approvals must be obtained from the Civil Protection Authority (fire prevention)
3-The factory must have its own separate entrances and exits.
4- A clear sign bearing the factory's name must be displayed
5- The height between the factory floor and the lower surface of the ceiling must not be less than 2.60 meters.
6-The floor of the facility must be at or above the level of the adjacent land, provided that sufficient precautions are taken to prevent water seepage into the factory, including the installation of a drainage network at a suitable distance to prevent contamination. In all cases, manufacturing and storage operations must not be located in a basement, except for utility networks and facilities.
7- The site of the industrial facility must conform to the layout -submitted to the Egyptian Drug

Authority. No modifications may be made to the site before submitting a request for the required modification and conducting a licensing inspection of the factory to ensure compliance with health and technical requirements.

8- It is preferable to have a generator connected to the factory's electrical circuit for emergencies only.

9- It is preferable to have an Uninterruptible Power Supply (UPS) for processes or steps that require uninterrupted power supply in time of need.

10-It is preferable to have an underground electrical connection (earthing) if needed

11-The spaces should be suitable for the number of employees

*** The requirements include three main areas and are applied according to the type of activity, whether production, assembly, or alignment:**

- First- Axis: Requirements specific to the factory's -personnel and the factory's technical requirements

- Second- Axis : Control of production inputs and components

- Third- Axis: Machinery and equipment

A) Special requirements for production factories

First Axis

1-Requirements for Personnel Working in the Facility

The same requirements applied to medical devices factories, which are based on international standards, are as follows:

"ISO 13485/2016 Medical devices - Quality management systems- Requirements for regulatory purposes"

6.2 Human resources: **Personnel performing work affecting product quality shall be competent based on appropriate education, training, skills and experience.** **The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel** **The organization shall:** **a) Determine the necessary competence for personnel performing work affecting product quality.** **b) Provide training or take other actions to achieve or maintain the necessary competence.** **c) Evaluate the effectiveness of the actions taken.** **d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.** **e) Maintain appropriate records of education, training, skills and experience (see 4.2.5)** **NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.**	**-يجب أن يكون الموظفون القائمون بأي اعمال تؤثر في جودة المنتج أكفاء ولديهم الأسس المناسبة من تعليم، وتدريب، ومهارات وخبرات.** **- يجب على المنشأة توثيق عملية تحقيق كفاءة ووعي الموظفين وتوفير التدريب المطلوب لهم.** **- يجب على المنشأة ما يلي:** **●تحديد الكفاءة اللازمة للموظفين القائمين بأي عمل يؤثر في جودة المنتج.** **●توفير التدريب أو اتخاذ اجراءات أخرى لتحقيق الكفاءة اللازمة أو الحفاظ عليها.** **●تقييم فعالية الإجراءات المتخذة.** **●التأكد من أن موظفيها يدركون أهمية أنشطتها وكيفية المساهمة في تحقيق أهداف الجودة.** **●الاحتفاظ بسجلات مناسبة عن التعليم والتدريب والمهارات والخبرات المناسبة.** **ملحوظة: تتناسب منهجية التحقق من الفعالية مع المخاطر المصاحبة للعمل الذي يتم توفير** **التدريب له.**

2-Technical requirements for the factory

These are divided into mandatory requirements and non-mandatory rules. However, the factory needs to implement 50% of the non-mandatory. This percentage makes the non-mandatory requirements and rules mandatory in order to obtain the license, as explained below:

Mandatory Requirements	Non-mandatory rules:
Separation of toilets from the gowning area Toilets must be located before the gowning area	Non-mandatory rules: A shoe rack (open stand) is available, one for street shoes and another for toilets.
Ventilation must be provided in toilets	
Air curtains and electrical insect zapper must be installed at all factory entrances directly facing the street	

A- Primary gowning areas

The area where street clothes are changed into factory clothes; it is unclassified

Mandatory Requirements	Non-mandatory rules:
Street shoes must be kept separate from shoes worn inside the factory	Designate separate lockers for streetwear and other factory clothes.
Adequate ventilation and adequate lighting are required and must be covered	No washing basin near production areas, but hand sanitizer should be provided (Disinfectant)
A step-over bench and metal lockers made from coated metal are required	
Walls and floors must be hard with smooth surfaces and no visible joints. (Stout, smooth, with no joints)	

A tight (rust-resistant) wire mesh must be installed over any ventilation opening	
Designate gowning area for ladies and another for men (if available)	

B- Warehouses

●Warehouses are divided into areas according to the nature of the final product and are divided based on the needs and size of the business, production components, and the nature of the final product into:

1-Receiving area
2-Raw materials storage area
3-Packaging materials storage area
4-Rejection area, which must be secured.
5-Semi-finished product storage area, if required by manufacturing needs
6-Finished product storage area
7-Storage area for any raw materials or products requiring special storage conditions, such as chemicals and hazardous materials, subject to approval from the licensing authority

●A covered area with a canopy is required to ensure that products or raw materials are not exposed to sunlight or any weather changes during loading from and to the warehouse.
A receiving area with the following requirements:
Equipped with an air curtain and electrical insect zapper
Ventilation should be the same as the rest of the warehouse

●Temperature and humidity ranges should be appropriate for the nature of the product, and temperature and humidity should be recorded periodically.
●Flooring must be suitable for the nature of the product.
All warehouse doors must be tightly closed to prevent the entry of dust and insects.
-Any ventilation opening must be covered with tight wire mesh, and the glass must be tinted to prevent direct sunlight.
Adequate lighting must be provided.
-There must be no direct water source in the storage area.
-Do not store directly on the floor with Pallets or non-flammable stands, and storage must be 60 cm below the ceiling and 20 cm away from the walls.
-If there is a separate storage area for finished products, all the above requirements must be met-

C. Laboratories: Laboratory requirements are determined according to the type of product being manufactured and its specific standard.
1-A documentation system must be in place that clearly outlines the analysis methods and product release requirements to ensure safety. A post-sales follow-up system must also be in place, adhering to international standards ISO 13485.
2-The product release documentation system must include a checklist based on the product specifications. The recipient must use this checklist to verify that the device conforms to its intended use, thus ensuring its usability.
3-A list of the equipment used by the manufacturer must be provided
4-Compliance with Decision No. 499 for the year 2021 issued by the Chairman of the Egyptian Drug Authority regarding Requirements for Unique Device Identification (UDI) for Medical Devices circulating in the local market, and its updates.
5- Compliance with the decision of the Chairman of the Egyptian Drug Authority, No. 642 for the year 2021, regarding labeling data for medical and laboratory devices and equipment, in vitro diagnostics, production components and inputs, and its updates

Regarding the microbiology laboratory: If the nature of the product requires manufacturing under controlled environmental conditions, the requirements for licensing medical devices factories shall be referred to.

D- Production areas shall be adhered to as follows, according to the nature of the product:
●Non-sterile medical product and used non-sterile: Production and packaging within a classified area are not required unless the manufacturing specifications stipulate this.
If any stage of manufacturing or production components require special conditions, these shall be taken into consideration.
- Manufacturing within a controlled room is not required unless the nature of the product necessitates it.
Controlled room: If the nature of the product necessitates it.
This is the area where the product is prepared and packaged, and the following requirements shall be observed:
○The controlled room must be separate (and not used as a passageway).
○If water is used in the production process, its entry and exit must be in a closed channel
○ gowning area must be provided before entering the premises.

cleaning area must be provided for cleaning and removing the outer packaging of raw materials before they enter the area. This area must have a ventilation source and an exhaust fan.

○A good indirect ventilation source is required (fans are not permitted). The temperature must be 30°C, and temperature monitoring devices must be present to ensure it does not exceed 30°C and humidity must not exceed 65%.

○The floors must be hard, smooth, and clean
○A designated storage area for storing molds, attached to the controlled area, should be provided as needed.
If the factory performs the package step in a separate area, all the requirements must be met.
Clean- room: If the nature of the product necessitates that:
If the manufacturing specifications or risk assessment study stipulate production within a clean area, the requirements for licensing medical devices factories must be applied. The same rules apply to the air handling unit. (HVAC system)

Second Axis: Control of Production Inputs and Components

The same current procedures are followed, which include maintaining a list of approved raw material suppliers according to the quality system, approved by the factory, and reviewing the certificates held by the suppliers and the analysis certificates and safety data sheet for the imported raw materials, in accordance with the guidelines of the Egyptian Drug Authority.

Third Axis: Machinery and Equipment
The compatibility of the machinery for the production process is reviewed by a joint inspection committee formed by the Industrial Development Authority and the Egyptian Drug Authority, in accordance with the licensing inspections stipulated in Law No. 15 of 2017 and Law No. 151 of 2019.

b) Special requirements for assembly and alignment factories

First Axis●

1-Requirements for Personnel Working in the Facility:

The requirements of the World Health Organization (WHO) and the International Standards for Prosthetics and Orthotics (ISPO) are followed
World Health Organization. (2005). Guidelines for training personnel in developing countries for prosthetics and orthotics services. World Health Organization

Prosthetics/orthotics professionals are usually part of a multi-disciplinary rehabilitation team. To ensure prosthetics and orthotics service users get a quality service, ISPO has taken several important steps to facilitate and enhance the education of all health care disciplines involved with prosthetics and orthotics throughout the world. **The Society has detailed appropriate education and training programs for the full professional prosthetist/orthotist (Category I), orthopedic or Prosthetist technologist (Category II) or bench worker (Category III). The philosophy and curricula are widely accepted by most of the international governmental and nongovernmental agencies in the field of rehabilitation and prosthetics/orthotics services. Category I and II personnel are responsible for direct service. Category III technicians/bench workers are also needed to support Category I and II personnel but are not considered as service providers.**	**يكون متخصصو الأطراف الصناعية والأجهزة التقويمية جزءاً من فريق التأهيل متعدد التخصصات.** **ولضمان حصول مستخدمي خدمة الأطراف الصناعية والأجهزة التقويمية على خدمة عالية الجودة اتخذت منظمة خطوات مهمة لتسهيل وتعزيز تعليم جميع تخصصات الرعاية الصحية المرتبطة بهذا التخصص في جميع أنحاء العالم.** **يتم تقسيم مقدمي الخدمة إلى عدة اقسام طبقاً للتخصص:** **الفئة الاولى: متخصصو الأطراف الصناعية / الأجهزة التقويمية المحترفون بالكامل.** **الفئة الثانية متخصص أطراف صناعية أو أجهزة تقويمية فني محترف.** **وتعتبر الفئة الأولى والثانية مسئولة عن الخدمة المباشرة.** **الفئة الثالثة عامل البدلاء وهو يقدم الدعم لموظفي الفئتين الأولى والثانية ولا يعتبر من مقدمي الخدمة.**

2-Technical requirements for the factory

These are divided into mandatory requirements and non-mandatory rules. However, the factory needs to implement 50% of the non-mandatory. This percentage makes the non-mandatory requirements and rules mandatory to obtain the license, as explained below:

Mandatory Requirements	Non-mandatory rules:
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4-Rejection area, which must be secured.
5-Semi-finished product storage area, if required by manufacturing needs
6-Finished product storage area
7-Storage area for any raw materials or products requiring special storage conditions, such as chemicals and hazardous materials, subject to approval from the licensing authority

An area covered with a canopy is required to ensure that products or raw materials are not exposed to sunlight or any weather changes during loading from and to the stores.
A receiving area with the following requirements:
Equipped with an air curtain and electrical insect zapper
Ventilation should be the same as the rest of the warehouse

●Temperature and humidity ranges should be appropriate for the nature of the product, and temperature and humidity should be recorded periodically.
●Flooring must be suitable for the nature of the product.
All warehouse doors must be tightly closed to prevent the entry of dust and insects.
-Any ventilation opening must be covered with tight wire mesh, and the glass must be tinted to prevent direct sunlight.
Adequate lighting must be provided.
There must be no direct water source in the storage area.
Do not store directly on the floor with Pallets or non-flammable stands, and storage must be 60 cm below the ceiling and 20 cm away from the walls.
If there is a separate storage area for finished products, all the above requirements must be met

C. Laboratories: Laboratory requirements are determined according to the type of medical supplies to be manufactured and their specific standard.

1-A documentation system must be available, outlining the analytical methods and release criteria for the product to ensure its safety. A post market follow-up system must also be in place, in accordance with international standards ISO 13485.
2- The product release documentation system must include a checklist detailing the product

specifications. The recipient uses this checklist to verify that the device conforms to its prescribed use, ensuring its usability.
3-A Surveillance system must be available at the factory, overseen by the treating physician, to ensure the product's safety and efficacy during use. The system's implementation mechanism is determined through a follow –up study of curricula stipulates post marketing based on risk (risk base study) for each product.

D. Production Areas: These are adhered to as follows, according to the nature of the product:

○The product is a non-sterile medical product and is used non-sterile: Production and packaging within a classified clean area are not required (unless the manufacturing specification stipulates otherwise)

If any stage of manufacturing or production components require special conditions, these requirements must be met.
Manufacturing takes place within a controlled area.
The area for measuring and taking patient measurements and testing the device:

During construction, the factory adheres to the Egyptian Code for the Design of External Spaces and Buildings for People with Disabilities.

<u>Second Axis</u>: Control of Production Inputs and Components
- The same current procedures are followed, which include maintaining a list of approved raw material suppliers according to the quality system and approved by the factory, reviewing the certificates held by the suppliers, and reviewing the analysis certificates for imported raw materials according to the mechanisms followed by the Egyptian Drug Authority.

<u>Third Axis</u>: Machinery and Equipment
The compatibility of the machinery for the production process is reviewed by a joint licensing inspection committee formed by the Industrial Development Authority and the Egyptian Drug Authority, in accordance with the licensing inspections stipulated in Law No. 15 of 2017 and Law No. 151 of 2019.

Note: -

If a factory fails to meet any of the above requirements due to the nature of the medical device, A study with references and justification must be submitted to the licensing committee

. A list of products must be submitted to the Egyptian Drug Authority, when applying for a license, and the Standard specifications required for manufacturing.

All factories should follow the guidelines for labeling of medical devices and laboratory supplies and equipment, in vitro diagnostics, and production components and inputs.

Fifth: references

1-WHO standards for prosthetics & orthotics (part 1 standards)
2- The European Union Medical Device Regulation - MDR
3- WHO (Guidelines for training personnel in developing countries for prosthetics and orthotics services World Health Organization2005)

4-ISO 13485:2016 Medical device - Quality Management System
5- ISO 14644:2015 Cleanrooms and associated controlled environments
6-Egyptian Code for the Design of Outdoor Spaces and Buildings for the Use of Persons with Disabilities, Code No. 106.

7- The guideline for labeling of medical devices , Laboratory Supplies and Equipment, and Production Components and production Inputs.
8-Decision No. 499 of 2021 issued by the Chairman of the Authority

9- Decision No. 642 of 2021 issued by the Chairman of the Egyptian Drug Authority

10-Law Establishing the Egyptian Drug Authority, No. 151 of 2019

11-ISO 14971:2019 Application of risk management to medical devices

12- MDD:93/42/EEC
13-Guidance Manual for Importing Medical Supplies of All Types
14- Guidance Manual for Using International Barcodes