Draft Decree No. …/2026, of ……., regulating the technical and health requirements for Aesthetic Medicine healthcare centres and services in the Region of Murcia.

In compliance with the provisions of Article 29.1 of Law 14/1986, of 25 April, on General Health, and Article 27.3 of Law 16/2003, of 28 May, on the cohesion and quality of the National Health System, Royal Decree 1277/2003, of 10 October, was approved, establishing the general bases for the authorisation of healthcare centres, services and establishments.

This Royal Decree regulates the general bases for authorising healthcare centres, services and establishments, and creates the General Register of Healthcare Centres, Services and Establishments, in which the authorisations, modifications, and notifications issued by the autonomous communities in matters of healthcare authorisation are recorded. Annex I sets out the classification of such health centres, services and establishments and Annex II sets out the definitions of health centres, clinical care units and establishments.

These regulations broadly define healthcare centres as organised sets of technical resources and facilities in which qualified professionals, by virtue of their official certification or professional authorisation, primarily carry out healthcare activities with the aim of improving people's health. Healthcare centres may comprise one or more healthcare services, which constitute their clinical care offering.

In turn, Royal Decree 1277/2003 of 10 October defines a health service as 'a clinical care unit, with a distinct organisation, equipped with the technical resources and qualified professionals, by virtue of their official qualification or professional authorisation, to carry out specific healthcare activities'. Annex II of the aforementioned Royal Decree defines the healthcare service or clinical care unit U.48 (Aesthetic Medicine) as the *clinical care unit in which a doctor is responsible for carrying out non-surgical treatments aimed at improving bodily or facial appearance.*

Within the scope of this Autonomous Community, the Region of Murcia holds, pursuant to Article 11.1 of the Statute of Autonomy, approved by Organic Law 4/1982 of 9 June, the competence for legislative development and execution in matters of health, hygiene, pharmaceutical regulation and hospital coordination in general,

including that of the Social Security system, without prejudice to the provisions of Article 149.1(16) of the Constitution.

The Regional Ministry of Health is the department of the Autonomous Community of the Region of Murcia responsible for proposing, developing and implementing the general guidelines of the Governing Council in the following areas: health, hygiene, pharmaceutical regulation and hospital coordination in general, including that of the Social Security system; drug addiction; the competence of execution in matters of pharmaceutical products and the management of clinical care provision legally attributed to the Autonomous Community of the Region of Murcia, and any other functions assigned to it by current legislation.

Article 6 of Law 4/1994, of 26 July, on Health in the Region of Murcia, attributed to the head of the Regional Ministry of Health the granting of administrative authorisations of a health nature, as well as the cataloguing, accreditation and maintenance of the registers established by the legal provisions in force, and in its final provision, authorised the Governing Council to issue any provisions it deemed necessary for the execution and development thereof.

Government Council Decree No. 349/2023 of 28 September, establishing the governing bodies of the Regional Ministry of Health, determines that the General Secretariat shall, in turn, assume the powers and functions corresponding to the Health Services Inspectorate in relation to the inspection of healthcare centres, services and establishments.

For its part, the Directorate-General for Health Planning, Pharmacy and Research is responsible for the health management of clinical care resources, including the authorisation, registration and accreditation of healthcare centres, services and establishments, and also exercises responsibility for the organisation of healthcare professions, including the accreditation of professionals, entities and training activities.

In view of the above-mentioned competences in the field of health, Decree No. 73/2004 of 2 July 2004 regulating the procedure for the health authorisation of healthcare centres, establishments and services and the register of regional healthcare resources was adopted. Likewise, Article 67 of Law 3/2009 on the rights and duties of users of the healthcare system in the Region of Murcia stipulates that the competent Regional Ministry for health must ensure that healthcare centres, services and establishments in the Region of Murcia meet the technical requirements demanded by

state and regional regulations according to their classification, and must be authorised and registered in the Register of Regional Healthcare Resources.

This regulation is in accordance with the principles for sound regulation referred to in Article 129 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, in particular the principles of necessity, effectiveness, proportionality, legal certainty, transparency and efficiency.

In accordance with the principles of necessity and effectiveness, it pursues a general interest such as improving patient safety and the quality of healthcare in the procedures included in the portfolio of services offered by centres and services dedicated to aesthetic medicine, and is the most appropriate instrument for ensuring that this is achieved.

It strictly contains the regulations essential for achieving the objectives pursued, after confirming that there are no other measures less restrictive of rights or that impose fewer obligations on the recipients, and is therefore in accordance with the principle of proportionality.

The principle of legal certainty is also observed, as the regulatory initiative is exercised in a manner consistent with the rest of the legal system, both national and European Union, to generate a stable, predictable, integrated, clear, and certain regulatory framework that facilitates its understanding and, consequently, the actions and decision-making of individuals and centres.

It also complies with the principle of transparency, given that prior to its processing it has been submitted to prior public consultation and, subsequently, the appropriate public hearing and information procedure was carried out. Similarly, the objectives of this initiative and its justification are set out in the explanatory part of the initiative. With regard to the principle of efficiency, it imposes only those technical and health-related obligations that are necessary to guarantee the suitability of the authorisations granted and the quality of clinical care provided in these centres.

In this regard, because this provision affects the rights and legitimate interests of citizens, a public consultation process has been carried out, involving the publication of the text on the Citizen Participation Portal of the CARM, on the ‘MurciaSalud’ health portal, and an announcement in the BORM.

Individual consultations have also been sought with bodies or organisations recognised by law whose rights or legitimate interests are affected by the regulation and whose purposes are directly related to their objective in the field of Professional Associations and Scientific Societies; etc.

For all these reasons, it is considered necessary to approve specific regulations governing the technical and health-related conditions and requirements applicable to Aesthetic Medicine Healthcare Units, with a view to clarifying and specifying the material and human resources that these clinical care units must possess in order to be authorised and to provide certain services, so as to safeguard the quality of healthcare and the safety of patients treated at these healthcare centres and services, without prejudice to the powers and responsibilities which, in accordance with the applicable regulations, correspond to the various healthcare professions.

Accordingly, in the exercise of the powers conferred by Article 22 of Law 6/2004 of 28 December on the Statute of the President and the Governing Council of the Region of Murcia and Article 14 of Law 7/2004 of 28 December on the Organisation and Legal Regime of the Public Administration of the Autonomous Community of the Region of Murcia, at the proposal of the Regional Minister for Health, and in agreement with the Legal Council of the Region of Murcia,

THE FOLLOWING IS DECREED:

CHAPTER I

General provisions

Article 1. *Purpose.*

The purpose of this decree is to regulate the health requirements, operational and organisational conditions, as well as the minimum structural, facility and equipment standards which, depending on the range of services and clinical care activities offered, must be met by Aesthetic Medicine healthcare centres or services located in the Autonomous Community of the Region of Murcia.

Article 2. *Scope of application.*

For the purposes of this decree, Aesthetic Medicine centres or services are defined as those healthcare centres or services that offer Aesthetic Medicine clinical care (U.48), in which a doctor is responsible for carrying out non-surgical treatments

aimed at improving the appearance of the body or face, in accordance with the definition set out in Annex II of Royal Decree 1277/2003 of 10 October, which lays down the general principles governing the authorisation of healthcare centres, services and establishments, located in the Region of Murcia.

Article 3. *Authorisations.*

1. Aesthetic Medicine centres and services are fully recognised as healthcare centres or services and are subject to the legal framework and the requirement for prior healthcare authorisation to operate, as set out in Law 14/1986 of 25 April on General Health and in Decree No. 73/2004 of 2 July, which regulates the procedure for the healthcare authorisation of healthcare centres, establishments and services and the register of regional healthcare resources in the Autonomous Community of the Region of Murcia.

2. Compliance with the requirements and conditions set out in this decree does not constitute an exemption from the obligation to comply with any other requirements, authorisations or licences that may be required by the applicable regulations.

3. Medicines and medical devices shall be prescribed, dispensed and/or administered in Aesthetic Medicine centres and services, in accordance with the applicable health regulations, the specific conditions and requirements set out in this Decree, as well as in Royal Legislative Decree 1/2015 of 24 July, approving the consolidated text of the Law on guarantees and the rational use of medicinal products, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 establishing common specifications for product groups without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council, on medical devices, and Royal Decree 192/2023 of 21 March regulating medical devices, insofar as applicable in accordance with the clinical care services provided.

Article 4. *Requirements for Aesthetic Medicine treatments.*

1. The treatments practised in Aesthetic Medicine healthcare centres and services of (U.48) shall be in accordance with medical knowledge endorsed by the scientific community and adhere to clinical practice based on current scientific evidence.

2. In all cases, aesthetic medicine treatments offered at the healthcare centre or service may only require topical or local anaesthesia.

Article 5. ***Identification and advertising.***

1. All aesthetic medicine centres and services must comply with Decree 309/2010 of 17 December, which establishes the identification system for healthcare centres, establishments and services registered in the Register of Regional Healthcare Resources, with the aim of guaranteeing users the right to information regarding their type, characteristics, services, quality indicators and accreditation.

2. To this end, they must have the following items and/or identification documents: an accreditation document, an up-to-date information guide and an identification plaque, which must be displayed outside, next to the main entrance to the Aesthetic Medicine practice or service.

3. The centre's trading name must not be misleading or likely to cause confusion regarding the provision of another healthcare or non-healthcare service or activity. Similarly, no other non-healthcare centre or service may use terms in its name that are used to identify healthcare centres, such as 'medical centres' or 'medical clinics or practices', etc.

4. The centre's opening and closing times must be displayed. If the Aesthetic Medicine clinic or service is located within a multi-purpose shopping centre or arcade or a multi-purpose healthcare centre housing other healthcare services, and its opening hours do not coincide with those of the other activities taking place there, the different opening hours must be displayed in a prominent place.

5. All centres are required to keep, at all times, complaint, suggestion and claim forms available to users, as required by the applicable consumer protection regulations, together with the corresponding notice informing users of their availability.

Article 6. ***Advertising.***

1. All Aesthetic Medicine centres and services must comply with the provisions of the basic national and regional regulations governing the advertising and commercial promotion of healthcare products or activities. To this end, all healthcare advertising, regardless of the medium or format in which it is produced, shall be subject to the system of prior administrative authorisation for healthcare advertising, which must be

granted by the Regional Ministry responsible for health, in accordance with the requirements and criteria established for the dissemination of advertising messages in Decree No. 7/2021 of 18 February, which regulates healthcare advertising in the Region of Murcia.

2. Advertising, including that carried out on websites, blogs and social media, must comply with criteria and conditions of accuracy and transparency, strictly adhering to authorised healthcare activities and avoiding any information that could be misleading, cause error or pose a risk to health. It must also be carried out with a gender perspective, avoiding sexist advertising.

4. Advertising that is not supported by scientific knowledge or evidence is prohibited in any type of centre, whether healthcare or non-healthcare, as is the advertising of any medicinal product.

4. Staff at the Aesthetic Medicine healthcare centre or service who take part in advertising must identify themselves by stating their professional status, regardless of the medium used for the advertising.

CHAPTER II

Structure and requirements of facilities and equipment

Article 7. *General requirements for Aesthetic Medicine centres and services.*

Without prejudice to any provisions that may be laid down in the relevant national legislation for each type of healthcare Centre, Facility and Healthcare Service, Aesthetic Medicine healthcare centres and services must meet the following general conditions and requirements:

1. They must have their own identity for the purposes of authorization and compliance with the requirements contained in this Decree.

2. They must comply with the regulations in force regarding accessibility and the removal of architectural barriers, as well as with health and safety measures and occupational risk prevention measures.

3. Floors, walls and ceilings in patient clinical care areas, as well as in the rest of the facilities and general services, shall be made of smooth, washable materials resistant to disinfectant products.

4. All facilities must be disinfected and in optimal condition. They must be well-ventilated and protected from dust and humidity. If they have windows or ventilation grilles, they must be protected against the entry of vectors. Metal elements must be resistant to oxidation.

5. The furniture in the facilities must allow for proper cleaning and disinfection.

5. Temperature, humidity, ventilation and lighting conditions must be appropriate to ensure the proper performance of the activities carried out therein.

Article 8. ***Structure and distribution of the common facilities.***

Aesthetic Medicine healthcare centres and services must have a reception area and waiting room, a clinical area, and an area for general facilities and services, duly signposted and differentiated, in accordance with the following configuration and requirements:

1. Reception area and waiting room:

It must have sufficient capacity and suitable furnishings to ensure the comfort of patients and their companions.

2. Clinical area:

a) The floors, walls and ceilings of the examination and treatment areas, which shall be made of smooth and washable materials, must be kept in an suitable state of repair and cleanliness.

b) The clinical area shall comprise both the consultation area and the examination and treatment area, and must be of sufficient size for the activities to be carried out. Where the separation between the two areas is only functional, the total surface area shall not be less than 10 m^2 with a minimum of 3 m^2 on its smaller side.

c) Where possible, the clinical area shall have natural ventilation and lighting. Artificial lighting shall be shall be of a cool white or daylight type and not less than 500 lux.

d) In areas where patients need to undress, spaces adapted for this purpose or changing facilities shall be provided, if the centre's capacity allows, equipped with the means to create a separate, distinct area (such as a screen, sliding door or similar, a coat hook and a bench or chair), to ensure the protection of the patient's privacy and intimacy. Patients shall be provided with appropriate clothing for certain examinations or clinical tests where these require the patient to remove their clothes, leaving them partially or fully naked.

e) The examination and treatment area shall be equipped with the necessary equipment and technical resources for the clinical care activities carried out therein. It must also be equipped with a hand sanitising system and disinfectant, or a washbasin with running water fitted with a touch-free tap, soap dispensers and single-use disposable towels, or individual air hand-drying systems, to ensure proper asepsis at all times.

f) There must be a cleaning and disinfection area, which must be independent or separate from the rest of the clinical area, depending on the treatments or procedures carried out in the centre.

~~g)~~ It shall have a controlled, adequate and secure space intended for the storage of medicinal products, in accordance with the provisions of Article 9(6).

3. General facilities and services area.

a) This area shall include the toilets, which will be equipped with a toilet, a washbasin, a liquid soap dispenser and either a hot-air hand dryer or disposable paper towels. In the case of Aesthetic Medicine centres or services located within a shopping arcade or multi-purpose shopping centre, or within a multi-speciality healthcare centre comprising various healthcare services, it may be authorised, on an exceptional basis —taking into account the nature and limited scope of the interventional techniques or potential adverse effects of the treatments or procedures offered by the centre—that the toilets be communal and shared with other commercial premises in the multi-purpose building or with other healthcare services within the multi-speciality healthcare centre. In such cases, these toilets shall be regarded as part of the premises, provided that they are located on the same floor and are easily accessible.

b) The area designated for general facilities and services shall also include the physical spaces set aside for a cleaning room, auxiliary equipment and machinery,

material storage, archives, water, gas and electrical installations, waste processing and storage, and changing rooms for the centre's staff.

c) Machinery capable of producing vibrations or noise pollution must be adequately insulated and soundproofed.

Article 9. *General Equipment.*

1. All healthcare centres and services falling within the scope of this Decree shall have the necessary equipment to carry out their healthcare activities properly.

2. In all cases, they must have, as a minimum, the following basic equipment: an examination couch, weighing scale, a stadiometer, a tape measure, a sphygmomanometer or blood pressure monitor, a stethoscope and a pulse oximeter.

3. Whenever diagnostic or treatment procedures are carried out that may pose adverse risks to the patient, such as the administration of medicines or the application of medical devices, the Aesthetic Medicine centre or service must ensure that emergency care is available by providing the basic life-support equipment and emergency medication as listed in the Annex.

4. All devices used in Aesthetic Medicine treatments must, as a general rule, be duly authorised and approved and bear the CE marking, which must appear on the labelling and in the product leaflet or manual, accompanied by a four-digit number identifying the Notified Body responsible for the assessment procedures, except in the case of equipment or devices for which Community legislation or national regulations expressly provide for exemptions. In all cases, the requirements regarding the use and handling of the equipment or devices in question shall be subject to the applicable national basic regulations on medical devices and, where applicable, to the instructions for the correct use of the equipment provided by the manufacturers, distributors or suppliers.

5. Where non-disposable equipment or instruments requiring sterilisation are used, the Aesthetic Medicine health centre or service shall have, in the preparation room for the equipment referred to in Article 8(2)(f), a steam autoclave with pressure and temperature controls and sufficient capacity to meet its needs. The material to be sterilised must be bagged or packaged before being sterilised. The packaging of the sterilised material must bear the date of sterilisation and its expiry date.

6. To ensure that medicines are stored and preserved correctly, the centre shall have a controlled, suitable and secure storage area with sufficient capacity suited to its needs, enabling medicines to be properly identified, classified, stored and monitored. Medicines required to treat urgent cases must be located within the clinical care facility.

Where heat-sensitive medicines and medical devices that require special storage and handling conditions are stored and used, a refrigeration system shall be provided, fitted with a maximum and minimum temperature gauge, and the temperature must be monitored. This can be achieved by keeping a record of maximum and minimum temperatures, or by using a continuous temperature monitoring system. The temperatures shall be appropriate to the storage conditions required for the medicinal products being stored. Depending on the volume, type and classification of medicines and healthcare products used, or the specific conditions governing their control and supervision, the healthcare centre must have a duly authorised medicine store, in accordance with Decree No. 435/2009 of 11 December, which implements the regulation of pharmacy services and the storage of medicines and medical devices in primary healthcare structures in the Region of Murcia and establishes the authorisation procedure.

Article 10. ***Specific equipment according to the services offered.***

Depending on the specific services and procedures included in the clinical care package, the following specific requirements shall apply:

1. Mesotherapy: They must have disposable syringes and needles, an induced injection system, and the necessary products and medicines for the application of this technique.

2. Injection of botulinum toxin type A for aesthetic purposes. The facility must have a storage area for medicines and medical devices, duly authorised for this specific purpose, equipped with a refrigerator for the exclusive use of the aesthetic medicine procedures carried out there, with restricted access and a temperature monitoring system in accordance with the provisions of Article 9.6. It shall be equipped with gloves, syringes, sterile disposable 30-gauge needles and a system for neutralising any remaining toxin in vials or syringes prior to disposal, as well as a sharps container for used needles in accordance with the applicable regulations. It shall also have at least one container of sodium hypochlorite solution, eye cleaning solution, epinephrine (adrenaline) or another anti-anaphylactic product.

3. Preparation of Platelet Rich Plasma (PRP): The centre must have the kit used to obtain PRP via the closed system, which bears the CE marking for that use and must have been notified to the Spanish Agency of Medicines and Medical Products (hereinafter AEMPS) in accordance with the provisions of the applicable regulations. It shall also be equipped with the medical supplies required to perform venipuncture and administer PRP to the patient, as well as the centre's own centrifuge, which is compatible with PRP tubes and features the following adjustable settings: rotation speed (RPM), relative centrifugal force (RCF) and duration.

4. Infiltration of dermal fillers: The centre must have the medical supplies required to perform the infiltration, as well as the the filler implant medical device intended for plastic, reconstructive and aesthetic purposes, bearing the CE marking, marketed in Spain and listed in the AEMPS register.

5. Facial lifting with tensor threads: The centre must have the medical supplies required to perform subcutaneous implantation, as well as biocompatible absorbable suture material, which is a CE-marked medical device legally marketed in Spain.

CHAPTER III.

Documentary requirements

Article 11. Patients' rights and guarantees. Specific provisions relating to minors.

1. Aesthetic Medicine centres and services must guarantee the rights and safeguards of patients and service users in accordance with applicable national and regional legislation, in particular the right to privacy, to clinical information and documentation, to informed consent, to data confidentiality, and to public participation and feedback in the form of complaints. Patient safety must also be ensured through the adoption of measures to ensure the unambiguous identification of the person, the safe use of medication and medical devices, safety in the use of equipment and medical devices, as well as in the prevention of healthcare-related infections.

2. Aesthetic Medical treatments for minors shall be limited to exceptional cases and will require a medical assessment of the risks and benefits. In such cases, the information provided in advance to enable the patient to give their written informed consent prior to aesthetic medical treatment must be clear and comprehensible and,

where appropriate, written in language suitable for the patient and, where applicable, their parents or legal representative.

Article 12. Clinical information and informed consent.

1. The Aesthetic Medicine centre or service shall ensure that patients have the right to receive clear and comprehensible information on all procedures affecting their health, so that they may give their consent freely and voluntarily.

2. Medical procedures and treatments that pose a risk or inconvenience to the patient with a significant and foreseeable negative impact on the patient's health shall require written informed consent, which shall be specific to each case and included in the medical record. The physician must be accurately and unambiguously identified in all reports and communications with the patient. The physician must not undertake any Aesthetic Medicine treatment requested by a patient if it is considered that the risk/benefit balance is not favourable, especially in those patients diagnosed with a body dysmorphic disorder, among others.

3. The content and requirements of the prior information and the informed consent form shall comply with the provisions of Articles 43 and 44 of Law 3/2009 of 11 May on the rights and duties of users of the healthcare system in the Region of Murcia.

4. The provision of consent in cases involving Aesthetic Medicine treatments for minors, as referred to in Article 11(2), shall comply with the provisions of Article 9 of Law 41/2002 of 14 November, the basic law governing patient autonomy and rights and obligations regarding clinical information and documentation.

Article 13. Patient identification and registration. Medical records.

1. A medical record must be drawn up for each patient and centre; it must be written legibly and its minimum content must comply with the provisions of Article 15 of the aforementioned Law 41/2002 of 14 November and other applicable regulations, in order to provide an accurate and up-to-date account of patients' state of health, progress, tests and treatments received.

2. Each healthcare centre shall have a system for archiving its patients' medical records, which shall document the procedures carried out. The retention and management of these records shall comply with the provisions of Chapter I of Title VI of the aforementioned Law 3/2009 of 11 May and other applicable regulations.

3. Healthcare centres shall ensure and be responsible for the safekeeping, preservation, use and right of access to patients' medical records and other clinical documentation, in accordance with the provisions of the applicable health regulations on clinical documentation and the protection of personal data. This must be reflected in the operational protocol set out in Article 14(e).

Article 14. Protocols or standard operating procedures.

Aesthetic Medicine centres or services must have standard operating procedures or protocols, in electronic or written form, covering the following activities and procedures:

a) The key treatment techniques and clinical care procedures offered as part of their range of services.

~~b)~~ The most frequent urgent situations and emergencies that may arise, and the appropriate measures to be taken, commensurate with the potential risks associated with their activities.

c) The transfer of patients, in the event of urgent situations, to other health centres for treatment.

d) Control relating to the storage, distribution and use of medicinal products and medical devices in accordance with the specific storage and preservation conditions applicable in each case.

e) The preservation, management and custody of medical records, including the necessary procedures and safeguards regarding the handling and custody of such records in the event that the Aesthetic Medicine centres or services cease to operate.

f) Cleaning, disinfection and, where appropriate, sterilisation of non-disposable material and instruments requiring sterilisation. The protocol must be up to date and supported by scientific evidence. It must include details of how the activity is organised, the methods used, the products employed, a list of items to be cleaned and sterilised, the frequency of the activity, the system for recording the activity using daily logs of the specified activity, and the responsibilities of the staff.

g) Identification, classification and internal management of clinical waste for those healthcare centres and services that generate it, ensuring that it is properly collected and disposed of by a waste management operator authorised by the competent authority, in accordance with applicable regulations.

h) Cleaning and disinfection of the facilities as well as daily logs of this activity.

Staff working at the healthcare centre or facility must know these protocols and follow them.

Article 15. Activity logs.

The Aesthetic Medicine healthcare centre or service must keep a record of its healthcare activities, at least in relation to the following services, treatments and activities:

1. Administration of botulinum toxin type A for aesthetic purposes. Conditions and requirements:

a) Medical staff administering this medication must complete a monitoring form stating the name of the healthcare professional, the date of administration and the dose administered, in accordance with the instructions issued for this purpose by the AEMPS. This form, duly updated, will be added to the patient's medical records.

b) In accordance with Article 10.2, the centre must have a duly authorized and specific medicinal products storage facility for the storage and supply of botulinum toxin type A for aesthetic use, which must meet the affiliation criteria and requirements set out in Decree No 435/2009 of 11 December.

c) Requests for toxins submitted to the pharmacy must be supported by the corresponding medical prescriptions, which will be kept at the healthcare centre and made available to the manager of the associated pharmacy so that they may carry out any checks they deem necessary.

d) Proof of delivery from the pharmacy to the healthcare centre and receipt by the centre shall be retained. This documentation must be signed by the manager of the pharmacy and by the person responsible for receiving the medicinal product at the facility, and must include, at least, the batch number, expiry date and confirmation that the cold chain for the medicinal product has been maintained.

e) The temperature of the cold store will be recorded daily, along with the maximum and minimum temperatures, and this information will always be available to the manager of the pharmacy to which the medicine storage facility is linked.

2. Administration of hyaluronidase as an emergency medicine. Requirements and conditions:

a) Medical staff administering this medication must complete a monitoring form stating the name of the healthcare professional, the date of administration and the dose administered. This form, duly updated, will be added to the patient's medical records.

b) In order to provide this treatment, the centre must also have an authorised medicinal products and medical devices storage facility in accordance with the regulations referred to in the previous paragraph.

c) As the medication is not currently available on the market in Spain, requests for it must be submitted via the specific procedure for "Request for Medicines in Special Circumstances (MSE)", as set out in the procedures and services guide of the Autonomous Community of the Region of Murcia, addressed to the competent authority responsible for pharmaceutical products.

d) It cannot be obtained through the preparation of a magistral formula, except in exceptional cases for a specific patient where commercially available medicinal products do not meet that patient's needs, given that a magistral formula cannot generally serve as a substitute for an authorized and marketed pharmaceutical speciality.

e) A record of its use must be kept, including: patient name, medical record number, dose, batch number, expiry date, date and time of application.

3. Preparation of Platelet-Rich Plasma (PRP). Requirements and conditions:

a) The medical professional will issue a prescription for the medicine, which will include precise instructions for the clinical use of the product.

b) Prior to the collection of blood and the application of the PRP, the patient's informed consent must be obtained in accordance with the applicable regulations.

c) The prescriber shall be responsible for ensuring the quality of PRP production and for implementing the necessary control, monitoring and traceability measures to prevent the transmission of infectious diseases.

d) A record must be kept of the procedures carried out, including: the patient's name, medical record number, date, time of procedure and requesting service. Laboratory tests to detect infectious agents must be carried out beforehand. This activity may not be subcontracted for processing at the centre.

4.Use of dermal filler implants. Requirements and conditions:

a) They must be authorised or registered with the Spanish Agency for Medicines and Medical Products.

b) Prior to the procedure, the patient must be provided with user instructions on how and when they may administer further injections at sites where a dermal filler implant has previously been injected, together with a copy of the annex referred to in point 6.2 of Annex IV to Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. The patient will be given the label that allows the traceability of the product, either as part of the informed consent or the document describing the procedure.

c) These products must not be used in persons under the age of 18.

5. Use of tensor threads: the patient's name and medical record number, the date and time of implantation, the area of placement, thread brand, batch number and expiry date must be recorded.

6.Sterilisation activities:

a) Quality control checks will be carried out on the sterilisation process for non-reusable equipment, comprising a physical and chemical check at each stage and a biological check at least once a week or in accordance with the frequency of use, and in all cases after any maintenance or repair operation on the autoclave.

b) These checks must be duly recorded in a logbook. The packaging of the sterilised material must bear the date of sterilisation and its expiry date.

Article 16. Inventory and maintenance of Electromedical equipment.

Any Aesthetic Medicine healthcare centre or service that possesses electromedical equipment must have the following documentation:

a) List of electromedical equipment, including: Brand, model and serial number; purchase invoice from the manufacturer/distributor; declaration of conformity of the medical device; technical specifications and operating and maintenance manuals, which must be written, at least, in Spanish, and the warranty documentation.

b) Preventive and corrective maintenance and/or calibration plan for the equipment, including: Records of periodic inspections as well as calibrations, accidents and breakdowns; type of control or repair carried out, its results, and corrective measures adopted.

c) Contracts for the provision of maintenance services, unless it can be demonstrated that the work is carried out using the organisation's own resources.

CHAPTER IV

Ownership. Staff requirements.

Article 17. *Ownership. Responsibility of the owner.*

1. Ownership of an Aesthetic Medicine healthcare centre or service may be held by a natural person or a legal entity; in the latter case, a legal representative must be appointed.

2. The owner or representative, as the case may be, shall be responsible for completing the necessary procedures and meeting the requirements to apply for and obtain, from the competent Regional Ministry of Health, the authorisations and registrations generally required of healthcare centres, services and establishments.

3. Regardless of the business and civil liabilities incumbent upon them as the owner of a business providing services to the public, such owners are also responsible for:

a) Holding the necessary health authorisations required by national and regional regulations governing the authorisation of healthcare centres, services and establishments.

b) Complying with and ensuring compliance with the provisions of this Decree, particularly in matters relating to staff, facilities and the necessary equipment, so as to enable healthcare professionals working at the centre to carry out their duties properly in accordance with the ethical principles of the profession.

c) Cooperating with the health authorities on any matters requested of them in relation to the activities of the healthcare centre or service.

d) Providing all information and documentation requested by the health authority when required.

e) The appointment and dismissal of the Technical Director and of any of their substitutes and assistants, where applicable.

f) Ensuring that the official qualifications or professional credentials of the staff employed are appropriate for the performance of their duties in relation to the activities carried out and their respective professional competencies as recognised by the applicable regulations; staff may not perform activities specific to a profession without the corresponding healthcare qualification.

g) Having professional civil liability insurance.

h) The procurement from manufacturers and/or distributors of the medical devices used, which meet the relevant requirements, where the manufacture of such products is subject to authorisation and their distribution is regulated.

i) Ensuring compliance with the principles and guidelines of good operational practice, occupational risk prevention regulations, and the quality systems required for the establishment, and providing the technical management with the necessary means to achieve this.

j) The advertising of the healthcare centre or facility, in accordance with the provisions of this decree and the applicable sector-specific regulations on healthcare advertising, which must be limited to authorised healthcare activities.

k) Any other obligations arising from their status as owner.

Article 18. Technical management and healthcare staff.

1. The activities and services carried out and provided at these healthcare centres and services must be conducted under the technical supervision, responsibility, monitoring and control of a Technical Director, who must hold a degree in Medicine and Surgery and also have specific training in Aesthetic Medicine, duly accredited through one of the following options:

a) Specific training comprising a university Master's degree or an equivalent official postgraduate qualification or institution-specific qualification, delivered by universities or university centres and healthcare organisations and institutions, which includes accredited in-person placements in Aesthetic Medicine and/or hair restoration, if the centre or department offers this, or in specific Aesthetic Medicine techniques in line with the range of services provided.

b) A specialist qualification in Plastic, Aesthetic and Reconstructive Surgery, or another surgical or medical-surgical speciality, whose official training programme demonstrates competence in aesthetic medicine that corresponds to the range of services offered by the healthcare centre or service.

In cases where the Aesthetic Medicine service is part of a multi-speciality healthcare centre comprising various healthcare services, the technical management of the multi-speciality healthcare centre may be carried out by another healthcare professional holding a qualification of equal or higher level to that required for the provision of the authorised clinical care services, valid throughout Spain, in accordance with the provisions of the legislation on healthcare professions and the relevant professional registration requirements where these are legally mandatory.

2. Aesthetic Medicine activities and services carried out at the healthcare centre or service must be performed in the continuous and permanent physical presence of the Technical Director or, where applicable, a substitute or assistant who meets the same qualification and professional practice requirements as those required of the Technical Director, but always under their supervision and guidance, such that the healthcare centre guarantees, at all times whilst providing or carrying out healthcare activities and services, that patient care is provided by a healthcare professional holding the appropriate official qualification and possessing the professional competences and skills required for the clinical care provided, in accordance with the definition of the healthcare provision, thereby ensuring patient safety.

3. The Technical Director may not perform such duties simultaneously, during the same public service hours, in more than one Aesthetic Medicine healthcare centre or service. Any changes or replacements of the person holding the post of Technical Director must be notified by the centre's owner to the regional health authority. In such cases, supporting documentation must be provided to confirm the new Technical Director's qualifications, professional registration, as well as their appointment and acceptance of the post.

4. The healthcare centres and services covered by this Decree must have sufficient healthcare staff to ensure they operate effectively. Such staff shall carry out the professional duties recognised by current legislation, subject to the specific requirements set out for each type of service provided by the Aesthetic Medicine centre or service.

. All other physicians holding a degree in Medicine and Surgery shall have the same training as referred to in paragraph 1.

6. Healthcare professionals must undertake continuing professional development courses that are duly accredited either by the Accreditation System for Continuing Professional Development in the Healthcare Professions or by the university through ECTS credits.

7. Centres may employ other healthcare professionals or vocational healthcare staff who perform specific procedures or assist with various activities at the centre; such individuals must hold the relevant qualifications or official accreditation and, where applicable, be registered with a professional body, thereby qualifying them to practise their profession, and they must always do so under the supervision and responsibility of a qualified doctor of medicine and surgery. These staff members must also undertake continuing professional development in this field through courses that have been accredited for this purpose. In any event, healthcare professionals who carry out or assist in the provision of certain treatments involving the use of any medical devices or equipment must have received the necessary training and instruction to ensure the safe and effective use of the device, the management of any incidents associated with the product, and the detection and subsequent handling of reportable incidents.

8. All qualified medical staff at the healthcare centre or service must be registered as practising members of the relevant professional body and must hold professional civil liability insurance that covers the practice of Aesthetic Medicine.

9. All staff working at an Aesthetic Medicine centre or clinic must wear a badge on their clothing that states their first name and surname, professional category and the role they hold at that centre.

Article 19. *Appointment of the Technical Director.*

The appointment of the Technical Director shall be made by the owner or legal representative of the healthcare centre or service, and shall be notified immediately to the competent authority responsible for the authorisation and registration of healthcare establishments, together with the following documents:

a) The appointment document, stating express acceptance of the position by the Technical Director, duly signed by both the Technical Director and the owner or legal representative.

b) Certificate confirming their registration with the professional body.

c) Academic qualifications accrediting their eligibility to exercise professionally the function of Technical Director, in accordance with the provisions of Article 18(1).

d) Declaration that the individual is not subject to any grounds of incompatibility.

Article 20. Responsibilities of the Technical Director.

1. The Technical Director has the following responsibilities:

a) Organising the running of the Aesthetic Medicine centre and taking responsibility for the clinical care provided therein.

b) Collaborating with the competent health authorities in the monitoring, inspection and control activities.

c) Monitoring advertising relating to healthcare activities carried out at the Aesthetic Medicine centre, ensuring it complies with the authorisations granted.

d) Ensuring the proper maintenance of the facilities, equipment and medical devices used in the establishment.

e) Execution and/or direct supervision of the application of medical devices where required.

f) Ensuring the legitimate origin of the products they manage or use.

g) Assessing and managing, within the scope of their responsibilities, any incidents detected with the medicinal products, medical devices and cosmetic products used, as well as reporting such incidents to the health authorities as part of the monitoring system.

h) Safeguarding and keeping up to date the records held at the Aesthetic Medicine centre, and in particular all matters relating to the operation, management and content of the medical records register.

i) The maintenance, monitoring and updating of the quality assurance system of the establishment.

j) Ensuring compliance with regulations on the prevention of occupational risks.

k) Any other responsibilities assigned by applicable legislation.

2. The Technical Director shall be directly responsible for the activities carried out in the Aesthetic Medicine centres, without prejudice to the responsibility of other health professionals, as well as the business responsibility of the owner. The responsibilities of the Technical Director in the exercise of their profession shall not, in any case, exclude any civil liability that may arise from the performance of those duties.

Article 21. *Replacement of the Technical Director.*

1. In the event of the Technical Director's absence due to exceptional and temporary circumstances, such as illness or non-permanent physical or mental incapacity, election to public office or corporate or professional representative positions, specialist studies or other similar circumstances which prevent the proper performance of their duties, a substitute may carry out those duties, provided that the substitute holds the same qualifications as those required of the Technical Director, in accordance with the provisions of Article 18.1.

2. Where such absence is likely to be prolonged, or where there is a change in technical management for any reason, the competent governing body must also be notified immediately, and the same documents as those specified in Article 18 must be provided.

Chapter V

Inspection and control

Article 22. Inspection and control.

The Health Authority responsible for healthcare centres, services and establishments is responsible for the monitoring, inspection and evaluation of Aesthetic Medicine centres and services, with a view to verifying compliance with the obligations and requirements set out in this decree and in all other applicable regulations. The competent staff carrying out inspection duties may conduct all manner of physical checks and take whatever action is necessary in accordance with the powers conferred by Law 14/1986 of 25 April, and Decree 15/2008 of 25 January, approving the Regulations Governing the Inspection of Healthcare Services in the Autonomous Community of the Region of Murcia.

The managers of Aesthetic Medicine centres and services, as well as all technical and support staff, must cooperate with the Inspectorate to facilitate the conduct of its inspections and provide all documentation and information requested.

Where the inspection concerns the medicinal products storage facility, the manager of the pharmacy linked to the storage facility at that clinic must be made informed from the outset. In such cases, any issues identified, requirements or notifications relating to the medicinal products storage facility shall be communicated simultaneously to both the pharmacy manager and to the managers of the aesthetic medicine centre or service, so that the necessary information can be provided or the deficiency rectified.

If, in the course of their duties, the Inspection Services detect a breach of the obligations set out in this decree, the matter shall be referred to the higher authority, which may initiate the corresponding disciplinary proceedings in accordance with the principles governing disciplinary powers and disciplinary procedures, as set out for this purpose in Law 39/2015 of 1 October, on the Common Administrative Procedure of Public Administrations and in Law 40/2015 of 1 October on the Legal Regime of the Public Sector.

Chapter VI

Penalties and intervention measures

Article 23. Penalty regime and intervention measures to protect public health.

Without prejudice to any liabilities that may arise, failure to comply with the obligations set out in this decree shall be subject, following the processing of the relevant administrative file, to the system of penalties and intervention measures provided for in Law 14/1986 of 25 April, on General Health; Chapter V of Decree 73/2004 of 2 July, regulating the procedure for the health authorisation of health centres, establishments and services and the register of regional resources; Chapter IV of Decree No. 7/2021 of 18 February, regulating healthcare advertising in the Region of Murcia; and Title IX of Royal Legislative Decree 1/2015 of 24 July, approving the consolidated text of the Law on Guarantees and the Rational Use of Medicines and Healthcare Products.

Sole additional provision Adaptation period.

Aesthetic Medicine centres or services with a U48 clinical care offering which, upon the entry into force of this decree, hold a valid operating licence, shall have a period of one year from the date of entry into force to comply with its provisions. This period may be extended for a further six months at the request of the interested party.

First transitional provision. Transitional regime for authorisation procedures for opening and modification.

Any applications for authorisation to open or modify Aesthetic Medicine centres or services that are pending at the time this decree comes into force shall be subject to the provisions set out therein. Notwithstanding the foregoing, in order to facilitate compliance with the requirements set out in this regulation, parties involved in ongoing procedures for the initiation or amendment of proceedings may apply for conditional authorisation, provided that they provide sufficient evidence of compliance with all the requirements laid down in the decree before the expiry of the adaptation period specified in the first additional provision.

Second transitional provision. Transitional regime for procedures for the renewal of the healthcare operating authorisation.

Renewal procedures for health operating licences that are pending at the time this regulation comes into force, as well as renewals that must be initiated during the transition period set out in the sole additional provision, shall also generally be subject to these regulations.

Notwithstanding the above, the managers of healthcare centres and services may request the renewal of their authorisation subject to compliance with any of the requirements set out in this decree. Such requirements must be fulfilled and accredited before the end of the aforementioned compliance period.

First final provision. Implementation and enforcement.

The head of the Regional Ministry responsible for health matters is authorised to issue any acts or instructions necessary to ensure the implementation and enforcement of the provisions of this Decree.

Second final provision. Entry into force.

This Decree will take effect one month after its publication in the Official Gazette of the Region of Murcia.

Issued in Murcia, on xx xxxxx 2026.—The President, Fernando López Miras.—The Regional Minister for Health, Juan José Pedreño Planes.

ANNEX

Basic equipment for the application of basic life support techniques and emergency medication

- Oropharyngeal (Guedel) airways of different sizes.
- Artificial ventilation unit: Self-inflating bag (3–5-litres), with a valve and a transparent face mask, featuring padded edges to facilitate an airtight seal.
- Oxygen equipment, comprising at least one compressed oxygen cylinder, fitted with a flowmeter, pressure regulator and suction system, enabling simultaneous and independent oxygen administration and the use of the suction function.
- Oxygen masks with adjustable FiO2.
- Rubber tubing for connection between mask and flowmeter.
- Unit comprising a stethoscope and a sphygmomanometer.
- Infusion set, intravenous catheter, syringes and needles.
- Adrenergic agents (injectable solution).
- Atropine.
- Antihistamines for systemic parenteral use.
- Glucocorticoids for parenteral use.
- Organic nitrates for sublingual administration.
- Benzodiazepines for parenteral use.
- Glucose and saline solutions.
- Single-dose glucose.
- Hyaluronidase (if hyaluronic acid is used).