Text consolidated by Valsts valodas centrs (State Language Centre) with amending regulations of:

7 January 2020 [shall come into force on 10 January 2020].

If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet

Regulation No. 182

Adopted 14 April 2015

**Regulation Regarding Hygiene Requirements for the Provision of Tattooing and Piercing Services and Special Requirements for Tattooing Products**

*Issued pursuant to*

*Section 38.1, Paragraphs one and three of the Epidemiological Safety Law, Section 21, Paragraph one of the Consumer Rights Protection Law, and Section 8.1 of the Law on the Safety of Goods and Services*

[*7 January 2020*]

**I. General Provisions**

1. This Regulation prescribes:

1.1. hygiene requirements for tattooing, including micro-pigmentation, permanent make-up, scarification and piercing services (hereinafter – the services), providers thereof, premises for the provision of such services, equipment of the premises and work accessories;

1.2. special requirements for tattooing products, and also procedures for the supervision and control thereof;

1.3. the requirements for the competence of the person employed in the provision of services in the field of hygiene;

1.4. the procedures by which the persons employed in the provision of services shall be trained in the field of hygiene;

1.5. the requirements for the training programme in the field of hygiene and the certificate issuer, and also a sample certificate and the procedures for the issuance thereof.

[*7 January 2020*]

2. The following terms are used in this Regulation:

2.1. tattooing – injection of a tattooing product into human skin, thus creating a consistent drawing;

2.2. micro-pigmentation and permanent make-up – injection of a micro-dose of tattooing product into the upper layer of human skin, thus creating a temporary consistent drawing;

2.3. scarification – process, during which scars are being created on the body by cutting or burning skin, and also by injecting tattooing product into the cut wounds;

2.4. piercing – perforation of skin, mucous membrane, muscle or gristle to create an opening for the insertion of jewellery;

2.5. tattooing product – substance or mixture intended for tattooing, scarification, creation of permanent make-up or micro-pigmentation;

2.6. to make available on the market – to supply the product for distribution, consumption or use in the European Union market for commercial activities in return for payment or for free;

2.7. to place on the market – to make a product available on the European Union market for the first time;

2.8. manufacturer – a natural or legal person who manufactures a product or upon whose assignment a product is designed or manufactured, and places on the market such product under his or her name or trademark.

3. Responsibility for meeting requirements of this Regulation lies with the economic operator who offers services (hereinafter – the service provider) or the person placing the tattooing product on the market or making it available on the market.

4. Prior to commencing the provision of services, the service provider shall notify the Health Inspectorate thereof in accordance with the laws and regulations regarding the procedures by which the service provider notifies of the commencement of economic activity related to the provision of beauty treatment services.

5. Implementation of this Regulation shall be controlled by the Health Inspectorate. Implementation of the requirements referred to in Paragraph 14 of this Regulation shall be controlled by the Consumer Rights Protection Centre and *valsts sabiedrība ar ierobežotu atbildību “Latvijas Proves birojs”* [the State limited liability company *Latvijas Proves birojs*].

**II. Requirements for Premises, Equipment Thereof and Work Accessories**

6. The following shall be provided at the place where the services are provided:

6.1. waiting room or place for a customer;

6.2. room for the provision of services;

6.3. room for the processing of work accessories or a place where hand washstand with running cold and hot water, disinfection equipment and sterilisation devices are placed;

6.4. toilet facilities, intended also for customers;

6.5. cleaning equipment storage facility.

7. Centralised or autonomous cold and hot water supply, as well as household sewerage system shall be provided on the premises.

8. Requirements for the micro-climate, venting and lighting of the work premises, auxiliary premises for personnel and first aid kit shall be provided in accordance with the laws and regulations regarding labour protection requirements in the workplaces.

9. Materials that can be easily cared for and disinfected shall be used for the finishing of premises, equipment and work surfaces.

10. Following items shall be in the premises for the provision of services:

10.1. couch or chair with waterproof, non-absorbent, easy cleanable material;

10.2. table for the work accessories;

10.3. closet for the storage of disinfected and sterile work accessories and work materials;

10.4. a cupboard or shelve for clean laundry;

10.5. litter bin with an opening system to prevent hands from contacting a potentially contaminated surface;

10.6. hand washstand equipped with liquid soap, disinfectant and single-use hand drying items;

10.7. separate, labelled, unbreakable and puncture-resistant container with a lid for sharp single-use work accessories.

[*7 January 2020*]

10.1 The service shall be provided in a separate room or enclosed location that is specially equipped for such purpose without the presence of unauthorised persons.

[*7 January 2020*]

11. Separate set of towels or napkins, single-use towels or single-use materials shall be used for the service of each customer.

12. Only sterile and single-use needles shall be used for the provision of services.

13. At least two sets of work accessories prepared for work shall be located at the place for provision of services.

**III. Requirements for Tattooing Products and Piercing Decorations and Procedures for their Labelling**

14. Decorations to be used for piercing shall be made of materials which do not cause allergy and which are safe to human health.

15. Tattooing products shall be sterile. If tattooing products are intended for multiple use, they shall be packed in suitable container which prevents contamination of tattooing products. The service provider shall prevent purification of a tattooing product during the use thereof.

16. Tattooing products shall be placed on the market, made available on the market or used for the provision of services, if information on quality contents thereof is available.

17. Only tattooing products the labelling of which contains the following information shall be allowed to be placed on the market, made available on the market or used for the provision of services:

17.1. type of use of the tattooing product;

17.2. name and address of the manufacturer and the person, who is responsible for the placing of the tattooing product on the market;

17.3. minimum validity period of the tattooing product. Month and year or day, month and year shall be indicated;

17.4. list of ingredients of the tattooing product, indicating the conventional (trivial) name of the chemical substance or the name according to the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC) or other internationally recognised nomenclature, including name in the International Nomenclature of Cosmetic Ingredients (INCI) or the colorant index (CI) number;

17.5. batch number, code of the tattooing product or other signs, which allow for identification of the batch of the tattooing product;

17.6. conditions of use and warnings of the tattooing product;

17.7. indication on sterility.

18. If necessary, labelling of the tattooing product shall include storage arrangements to be complied with for the tattooing product to retain its specific properties and functions within the set minimum validity term.

19. If, due to practical reasons, information referred to in Sub-paragraphs 17.4 and 17.6 of this Regulation may not be indicated on the packaging, such information shall be included into the annotation, card, ribbon or label attached to the tattooing product.

**IV. Procedures for the Maintenance, Disinfection and Sterilisation of the Premises, Equipment Thereof and Work Accessories**

20. All the premises and equipment placed therein shall be maintained in clean and working order. The service provider shall develop a plan for the cleaning, disinfection, and sterilisation of equipment and work accessories in accordance with Annexes 1 and 2 to this Regulation.

[*7 January 2020 / See Paragraph 39*]

21. The premises shall be cleaned up at least once a day applying washing and cleaning detergents. Toilet facilities shall be cleaned by applying a separate, marked cleaning equipment.

[*7 January 2020*]

22. Surfaces contaminated with blood or other biological liquids shall be treated with disinfectant complying with its instruction of use. Table of work accessories, as well as surface of couch or chair shall be disinfected after every customer.

23. Surface of couch or chair shall be covered with a single-use or linen sheet to be changed after servicing of every customer.

24. The used laundry shall be collected and stored in separate bags or containers with a lid until washing. The laundry shall be washed in an automatic washing machine at a temperature of at least 60° C. If the laundry is contaminated with blood or other biological liquids, it shall be washed with disinfecting detergents.

[*7 January 2020*]

25. The service provider shall ensure the processing of multi-use work accessories in accordance with the cleaning, disinfection and sterilisation plan referred to in Paragraph 20 of this Regulation and Annex 1 to this Regulation.

[*7 January 2020*]

25.1 The service provider shall not use ultra-violet radiation equipment and ultrasound equipment for the sterilisation of work accessories. Ultra-violet radiation equipment may be used only for maintaining the level of disinfection achieved.

[*7 January 2020 / Paragraph shall come into force on 1 April 2020. See Paragraph 39*]

25.2 The service provider shall ensure sterilisation of work accessories taking into account the sterilisation mode specified in the instructions for the use of the sterilisation equipment and the instructions of the manufacturer of the work accessories. The service provider shall choose such sterilisation methods which ensure the destruction of viruses (hepatitis B, C, HIV), fungi, bacteria (such as a TB causative agent) and their spores using saturated steam sterilisation (autoclaving) or hot air sterilisation.

[*7 January 2020*]

25.3 The service provider shall store the disinfected and sterilised work accessories separately from the used accessories, ensuring that the clean work accessories do not come into contact with the used work accessories.

[*7 January 2020*]

26. The service provider shall ensure recording of disinfected and sterilised work equipment after every disinfection and sterilisation of multi-use work equipment. The date, type of disinfection, and time for the disinfection of work accessories shall be indicated when performing disinfection. The date, type of cycle, and time for the sterilisation of work accessories shall be indicated when performing sterilisation (also in the packaging). The service provider shall perform quality control of the steriliser operation in accordance with the requirements of the manufacturer of the equipment and document it.

[*7 January 2020*]

27. The used single-use work accessories which have come into contact with blood, other biological liquids or body tissue shall be placed into a litter bin with a lid. Sharp single-use work accessories shall be put into a separate, relevant and easy accessible jab-resistant container with a lid immediately after use. A container shall be transferred for destruction as soon as it has been filled up by three quarters. The service provider shall ensure waste collection in accordance with the laws and regulations regarding waste management.

27.1 Only such work accessories, materials, and cosmetic products which conform to the requirements of this Regulation and the laws and regulations regarding the requirements applicable in the field of cosmetic products, as well as with the purpose of their use and which do not cause harm to human safety and health, and also are provided with the manufacturerʼs instructions shall be used .

[*7 January 2020*]

**V. Requirements for Service and the Service Provider**

[*7 January 2020*]

28. The service provider shall be responsible for the provision of a service that is safe and non-harmful to human health . The service provider shall have proper knowledge of hygiene requirements for the provision of tattooing and piercing services. Such knowledge shall be attested by a document of medical education, a document of vocational education or qualification corresponding to the provision of services which has been recognised in Latvia in accordance with the laws and regulations regarding the regulated occupations and recognition of vocational qualification, or a certificate on the completion of the 18 hour training programme “Minimum hygiene requirements determined for the provision of tattooing and piercing services” (Annex 3).

[*7 January 2020*]

28.1 A certified health care practitioner is entitled to conduct training in accordance with the programme indicated in Annex 3 to this Regulation, if necessary, involving in the training a practising provider of the concerned services who has a document of vocational education or qualification corresponding to the provision of services which has been issued by a licensed and accredited education programme (the size of which is at least 160 hours).

[*7 January 2020 / Paragraph shall come into force on 1 April 2020. See Paragraph 39*]

29. In accordance with Annex 4 to this Regulation, a certificate shall be issued by an institution which is entitled to provide training if a person has completed the training programme “Minimum Hygiene Requirements determined for the Provision of Tattooing and Piercing Services” and has passed the knowledge examination.. The certificate shall be valid for five years. The certificate shall be issued repeatedly after repeated acquisition of the training programme. The institution which is entitled to provide training shall keep records of the trainings organized in accordance with the programme indicated in Annex 3 to this Regulation. The records shall be kept for six years and they shall include the following information – name of the training programme and the number of hours, topics of the training programme, given name, surname, and signature of the teacher, given name, surname and signature of the training participant, and the date and number of the issued certificate.

[*7 January 2020*]

30. Provision of services to a customer with obvious signs of a skin or mucous membrane disease shall be prohibited, unless the customer presents a statement of a physician which certifies that this person is allowed to receive the service.

[*7 January 2020*]

31. Before providing a service, the service provider shall provide the customer information on tattooing products (name, composition, batch number, manufacturer, importer) or jewellery, care for the wound, healing period and possible complications, for example, allergic reactions, inflammations, bacterial, viral and fungal infections, and also on tattoo removal possibilities. After provision of service, the service provider shall issue a written summary of the abovementioned information to the customer.

[*7 January 2020*]

32. A customer shall fill in a survey form before the receipt of a service. The service provider shall include at least the information referred to in Annex 5 of this Regulation in the survey form. The service provider shall ensure that the survey form and information included therein cannot not be accessed by persons unrelated to the provision of services. The service provider shall keep filled in survey forms for two years.

[*7 January 2020*]

33. Before providing a service to a person who is younger than 18 years of age, the service provider shall verify that the person concerned has received a consent for the receipt of service from at least one of his/her parents or legal representative.

[*7 January 2020*]

34. Prior to the procedure, the service provider shall clean the skin of the customer and disinfect it using skin disinfectant.

[*7 January 2020*]

35. The service provider shall comply with personal hygiene requirements, use and change working clothes according to the specific character of the work to be performed. If contamination of clothes with blood or other biological liquids is possible, the service provider shall use a single-use apron.

[*7 January 2020*]

36. The service provider shall wash and disinfect his or her hands before and after provision of service. If contact with injured skin, blood and other biological liquids is possible, single-use gloves shall be used for the servicing of each customer.

[*7 January 2020*]

36.1 Waterproof gloves shall be used when washing, cleaning, and disinfecting work accessories and surfaces, as well as washing dirty laundry. Puncture-resistant gloves hall be used when collecting and transporting waste.

[*7 January 2020*]

**VI. Closing Provisions**

37. This Regulation shall come into force on 1 January 2016.

38. Paragraphs 17, 18 and 19 of this Regulation shall come into force on 1 June 2016.

39. The requirement referred to in Paragraph 20 of this Regulation to develop a cleaning, disinfection and sterilization plan in accordance with Annexes 1 and 2 to this Regulation and Paragraphs 25.1 and 28.1 of this Regulation shall come into force on 1 April 2020.

[*7 January 2020*]

**Informative Reference to the European Union Directive**

Legal provisions have been coordinated with the European Commission and the Member States of the European Union in accordance with the Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations.

Prime Minister Laimdota Straujuma

Minister for Health Guntis Belēvičs

**Annex 1**

Cabinet Regulation No. 182

14 April 2015

**Breakdown of Services Equipment and Work Accessories by the Potential Risk of Infection**

[*7 January 2020*]

|  |  |  |  |
| --- | --- | --- | --- |
| **Classification1** | **Cleaning**2 | **Disinfection**3 | **Sterilization**4 |
| **1. Low risk of infection** |
| Has no direct contact with the skin of the customer or has contact only with healthy (undamaged) skin | Wash in warm water with a washing product, rinse in running water Drain | Disinfect with a low level disinfectant5 if there is a contact with the skin of a customer | – |
| Intended for contact only with healthy (undamaged) skin, but accidental contact with damaged skin is possible | Wash in warm water with a detergent, rinse in running water Drain | Disinfect with an intermediate level disinfectant6 | – |
| **2. Medium risk of infection** |
| Has contact with damaged skin, mucous membranes, and blood but does not pierce skin or mucous membrane | Wash in warm water with a washing product, rinse in running water Drain | Disinfect with a high level disinfectant7 | If necessary8 |
| **3. High risk of infection** |
| Pierces the skin or mucous membrane, enters sterile tissue or is used to hold other sterile instruments | Wash in warm water with a washing product, rinse in running water Drain | Disinfect with a intermediate or high level disinfectant | Autoclaving9 |

Notes.

1 Equipment and work accessories shall be treated successively in accordance with the risk category – low, medium or high – taking into account cleaning, disinfection and sterilization activities.

2 Ultrasound equipment may be used for the cleaning of multi-use work accessories in accordance with its instructions for use.

3 Disinfection shall be performed in a labelled container intended for this purpose (if the work accessory may be soaked or treated with a disinfectant available in a spray form). If, in accordance with its instructions for use, the work accessory, including parts and surfaces of the equipment, may not be soaked, a spray disinfectant or disinfectant napkins shall be used or it shall be wiped with a cloth moistened with 70 % alcohol solution. Disinfection shall be performed in accordance with the instructions for use of the disinfectant – adequate concentration shall be ensured and the exposure (effect) time of the disinfectant shall be taken into account. The disinfectant shall cover the entire surface of the work accessory. Disinfection shall not be performed by an ultrasonic cleaner and ultraviolet radiation (UV) equipment.

4 Sterilisation is the destruction of micro-organisms and their spores using methods verified to be capable of destroying micro-organisms and their spores, taking into account the prescribed exposure time (the sterility assurance level (SAL), or the likely presence of a surviving micro-organism able to reproduce on the surface of the work accessory after the sterilisation process is 10-6 SAL). The sterilisation process shall not be provided by UV equipment, ultrasonic cleaner, glass/quartz bead steriliser, boiling, microwave ovens, pressure boilers.

5 Low-level disinfection – destruction of bacteria (e.g. *S. aureus, P. aeruginosa)*, parts of fungal (e.g. *Aspergillus, Candida*) and coated viruses (e.g. human immunodeficiency (HIV), herpes, hepatitis B and C), taking into account the exposure time specified in the instructions for use of the disinfectant.

6 Intermediate level disinfection – destruction of bacteria, coated and some uncoated viruses, mycobacteria and fungi, except for the destruction of bacterial spores, taking into account the exposure time specified in the instructions for use of the disinfectant.

7 High-level disinfection – destruction of bacteria, coated and uncoated viruses (for example, polio, coxsackievirus), mycobacteria, fungi and some bacterial spores, taking into account the exposure time specified in the instructions for use of the disinfectant.

8 Sterilisation, including with hot air sterilisation equipment, shall be performed if the service provider wishes to provide additional safety.

9 Hot air sterilisation equipment shall be used only for treating such work accessories which will not be used in invasive manipulations when providing a high-risk service.

**Annex 2**

Cabinet Regulation No. 182

14 April 2015

[*7 January 2020*]

**Structure of the Plan for the Cleaning, Disinfection, and Sterilisation of Services Equipment and Work Accessories**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Level of infection risk | Work accessories, equipment | Activities to be performed, regularity | Performer of work | Place of work performance |
| High risk of infection |  |  |  |  |
| Medium risk of infection |  |  |  |  |
| Low risk of infection |  |  |  |  |

**Annex 3**

Cabinet Regulation No. 182

14 April 2015

**Training Programme**

**“Minimum Hygiene Requirements Determined for the Provision of Tattooing and Piercing Services”**

[*7 January 2020*]

|  |  |  |
| --- | --- | --- |
| No. | Topic | Duration of training (minutes) |
| 1. | Human anatomy and physiology | 120 |
| 1.1. | General constitution of human body |
| 1.2. | Skeletal and muscular system and its functions |
| 1.3. | Circulatory and lymphatic system |
| 1.4. | Nervous system |
| 2. | Dermatology | 180 |
| 2.1. | Skin composition, structure and functions |
| 2.2. | Skin diseases |
| 3. | Allergies, their relation to the provision of tattooing and piercing service | 60 |
| 4. | Infectious diseases and risk thereof during the provision of tattooing and piercing services | 120 |
| 5. | Measures for the reduction of the risk of infection | 180 |
| 5.1. | Personal hygiene (requirements for the clothing and use of gloves) |
| 5.2. | Hand washing and disinfection methods |
| 5.3. | Disinfection and sterilisation of work accessories, methods thereof |
| 5.4. | Maintenance of the premises for the provision of services and equipment |
| 6. | Materials to be used for the tattooing and piercing and safety requirements thereof | 120 |
| 7. | Risk groups and contraindications for the reception of tattooing and piercing services, complications and their prevention | 120 |
| 8. | Provision of first aid in cases of health disorders caused by tattooing and piercing services | 60 |
| 9. | Requirements of laws and regulations binding on the providers of tattooing and piercing services | 60 |
| 9.1. | Laws and regulations regarding the safety of products and services |
| 9.2. | Laws and regulations regarding chemical substances and biocides |
| 9.3. | Laws and regulations regarding essential requirements for cosmetic products |
| 9.4. | Laws and regulations regarding waste management and collection of hazardous waste |
| 10. | Test of the acquired knowledge | 60 |

**Annex 4**

Cabinet Regulation No. 182

14 April 2015

[*7 January 2020*]

**Certificate for the Completion of the Training Programme “Minimum Hygiene Requirements Determined for the Provision of Tattooing and Piercing Services”**

|  |  |  |  |
| --- | --- | --- | --- |
| Issued to |  |  |  |
|  | (given name) |  | (surname) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Personal identity number |  |  |  |  |  |  | - |  |  |  |  |  |  |

|  |  |
| --- | --- |
| Head of the training programme |  |
|  | (given name, surname) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Personal identity number |  |  |  |  |  |  | - |  |  |  |  |  |  |

|  |  |
| --- | --- |
| Amount of the training programme (in hours) |  |
| Date of issue |  |
| Signature of the head of the training programme |  |
| Institution issuing the certificate |  |
|  | (name of the institution, |
|  |
| address, registration number assigned by the Enterprise Register of the Republic of Latvia) |
| Signature of the head of the institution |  |

Place for stamp

Certificate has been issued pursuant to Cabinet Regulation No. 182 of 14 April 2015, Regulation Regarding Hygiene Requirements for the Provision of Tattooing and Piercing Services and Special Requirements for the Tattooing Products.

**Annex 5**

Cabinet Regulation No. 182

14 April 2015

[*7 January 2020*]

**Customer Survey Form**

Name of the service provider and address of the place where the service is provided

|  |
| --- |
|  |
|  |

If you have been diagnosed any of the following diseases, please, consult a physician specialist regarding possibility of provision of the service.

|  |  |  |
| --- | --- | --- |
| • haemophilia | • eczema/psoriasis | • diabetes |
| • epilepsy | • herpes | • tuberculosis |
| • infectious diseases | • blood coagulation disorders | • heart diseases |
| • asthma |  |  |

Please, indicate, if:

|  |  |
| --- | --- |
|  | you are allergic (for example, to latex, cosmetic products, plasters, jewellery materials) |
|  | you have previously had complications during similar procedures (for example, tattooing, piercing, micropigmentation, permanent make-up, scarification. etc.) |
|  | you are taking medication (for example, antibiotics, antivirals, corticosteroids) |
|  | you are pregnant or breastfeeding |
|  | you have other conditions that are relevant for the receipt of the service (frequent dizziness, fainting, increased pigmented skin formations, skin formations that have changed etc.) |

Please, confirm:

|  |  |
| --- | --- |
|  | I am 18 |
|  | I am younger than 18. My parents (one of the parents, legal representative) have consented to conducting the procedure |
|  | I have been informed of the procedure, used materials and possible complications |
|  | I undertake to comply with the safety requirements to reduce the possible risks of complications |
|  | I agree |  | to receipt of the service |
|  | (type of the service) |  |
|  | The provided information is true |

|  |  |
| --- | --- |
| Given name, surname of the customer |  |

|  |  |
| --- | --- |
| Signature of the customer |  |

|  |  |  |
| --- | --- | --- |
| Date |  |  |