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Tattooing — Safe and hygienic practice

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National foreword

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NORME EUROPÉENNE

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Tattooing - Safe and hygienic practice

Tatouage - Bonnes pratiques d'hygiène et de salubrité

Tätowieren - Sichere und hygienische Praxis

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European foreword

This document (EN 17169:2020) has been prepared by Technical Committee CEN/TC 435 “Tattooing services”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2020, and conflicting national standards shall be withdrawn at the latest by July 2020.

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Introduction

This document provides requirements and recommendations on hygienic and safe tattoo practice to protect both the client and the tattooist against infection. It is essential to minimize infection risks caused by tattooing to clients, tattooists and others working in tattoo premises by use of appropriate hygiene procedures. Anyone carrying out tattooing is bound to be responsible for their own, their clients' and others' safety in respect of the tattooing process.

It is essential to also apply relevant European and national regulations, where they exist.

The verbal forms "shall" and "shall not" are used to express requirements.

The verbal forms "should" and "should not" are used to express recommendations.

The verbal forms "may" and "need not" are used to express permission.

The verbal forms "can" and "cannot" are used to express possibility and capability.

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1 Scope

This document specifies hygiene requirements before and during tattooing and for aftercare. It gives guidelines for tattooists and their routine interactions with clients and public authorities. It gives guidelines for the correct procedures to be used to ensure optimum protection of the client, the tattooist and others in the tattoo work area.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 374 (all parts), *Protective gloves against chemicals and micro-organisms*

EN 455 (all parts), *Medical gloves for single use*

EN 1500, *Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)*

EN 13060, *Small steam sterilizers*

EN ISO 11607-1, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1)*

EN ISO 17665-1, *Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1)*

EN ISO 23907-1, *Sharps injury protection - Requirements and test methods - Part 1: Single-use sharps containers (ISO 23907-1)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
aftercare
care process following tattooing to promote optimal healing

3.2
body fluids
fluids such as blood, serum and other fluids that may be contaminated with these substances that present a risk of infection transmission in the context of tattooing

Note 1 to entry: Bodily fluids such as tears, sweat or vomit do not present a specific tattooing hazard.

3.3
cleaning
removal of foreign materials from a surface

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3.4
connector cable
clip cord
electrical cable connecting power supply and drive unit for tattooing

3.5
convention
any premises or place used on a temporary basis for an event such as an exhibition, fair, festival or similar type of arrangement where tattooing is intended to be provided to the public with or without payment

3.6
disinfectant
chemical that is able to produce a defined reduction of specific microorganisms under defined conditions

Note 1 to entry: The Biocidal Products Regulation, as per 1 September 2013 (BPR, Regulation (EU) 528/2012), with a transitional period for certain provisions, will apply to relevant disinfectants.

3.7
disinfection
act of disinfecting, using controlled techniques, that reduces the number of microorganisms to a level safe for that particular application

3.8
drive unit
motor used to power tattoo apparatus

3.9
grip
textured surface cylinder which connects tube and tip intended to provide a secure grasp for the tattooist during the process of tattooing

3.10
hand hygiene
process used to inactivate or remove transmittable microorganisms on hands regardless of the resident skin flora

3.11
high risk equipment
equipment that penetrates the skin, comes into contact with broken skin and/or body fluids or may contaminate items that do so (e.g. needle holder, tube, grip, tip)

3.12
hygienic hand rub
product (liquid, gel or foam) applied to hands and rubbed to dryness intended to inactivate transmittable microorganisms regardless of the resident skin flora

3.13
ink cap
cap that contains tattoo ink

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3.14
ink cap tray
tray with recesses to hold a number of ink caps

3.15
needle bar
rod connecting tattoo machine and needle

3.16
needle cartridge
single use item containing needle and housing

3.17
personal protective equipment
special device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards

[SOURCE: IEC 82079-1:2012, 3.27]

3.18
pre-treatment
treatment of equipment to aid subsequent effective cleaning, disinfection and/or sterilization

3.19
sharps disposal container
container designed for the safe containment and disposal of sharps such as tattoo needles

3.20
single use
product intended to be used once and then discarded

[SOURCE: EN ISO 11810:2015, 3.18]

3.21
skin preparation
procedure for cleaning, disinfecting and, where necessary, shaving the skin prior to tattooing

3.22
steam sterilizer
autoclave
device using super-atmospheric steam at over 100 °C in a validated process to render processed items sterile

3.23
stencil
device allowing the transfer of a drawing onto the skin

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3.24
sterile
free from viable microorganisms

[SOURCE: EN ISO 11139:2018, 3.271]

3.25
sterilization
validated process used to render product free from viable microorganisms

[SOURCE: EN ISO 11139:2018, 3.277 – modified: Note 1 omitted]

3.26
sterilization container
container that allows sterilization of the contents and protects that sterility afterwards whilst it remains unopened for a defined time period

Note 1 to entry: The time period should be specified by the manufacturer of the container or, in the absence of such instruction for use, should be a period of no longer than six months.

EXAMPLE Pouches and boxes.

3.27
tattooing
procedure that penetrates the skin or mucous membrane for the purpose of insertion of tattoo ink to create a permanent or long-lasting design

3.28
tattoo machine
fully assembled device that produces reciprocal movement of a tattooing needle

EXAMPLE Coil machine, rotary machine, permanent make-up pen, manual operated device, handle.

3.29
tip
tapered hollow cylinder that holds and guides a tattooing needle during the tattooing process

3.30
tube
hollow cylinder through which the needle bar passes

3.31
ultrasonic cleaner
device that cleans by immersion aided by ultrasonic energy

3.32
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[SOURCE: EN ISO 17664:2017, 3.20]

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4 Responsibilities for the business owner/operator

4.1 General requirements for the business owner/operator

Business owners/operators shall be responsible for ensuring that the necessary registrations and licences required for the business are in place and copies of all relevant documents are available for inspection.

The owners/operators of a tattooing business shall document, maintain and update a procedures manual to ensure that good practice is used in the premises.

The content of the manual should include, but is not limited to:

— hand hygiene;

— the use of personal protective equipment;

— the management of exposure to body fluids;

— the cleaning and disinfection of tattoo premises (including all equipment and surfaces);

— waste management;

— aftercare procedures.

Where the business carries out sterilization, documented procedures shall be available for:

— the validation of the sterilization process;

— the method of inspection of packing and seals, copies of sterilizer maintenance details and verification records;

— the storage facilities and practices for sterile packs.

4.2 Training

Business owners/operators providing tattooing services shall ensure that all staff are trained commensurate with their activities. Training may be provided by the authorized operators according to national regulations, where they exist, using documented procedures that address the activities of the business.

All persons undertaking tattooing shall have received training in the following areas:

1) the basics of hygiene including hygiene for personal and client safety as well as environmental hygiene such as cleaning and disinfection;

2) sterilization procedures, if the tattooist carries out sterilization of equipment;

3) the basics of microbiology and relevant infection prevention;

4) the anatomy of the skin and basics of wound care, and contraindications;

5) the principles of occupational health and safety;

6) first aid, including potential infection due to unintended needle-stick injuries;

7) an understanding of legal and other relevant requirements applicable to the business activities.

Information regarding the content of the basic framework for training is given in Annex A.

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The curriculum shall be delivered in a manner to achieve the learning objectives as outlined below.

The objective of the training is to provide comprehensive knowledge of the content of this document such that it can be put effectively into practice.

The training shall include:

— the curriculum as specified in this document;

— at least one day of practical training; and

— an assessment by a competent person in an appropriate environment.

A refresher course to maintain competence and update previous training shall be undertaken at least every five years. A record of training received by all persons undertaking tattooing shall be retained and updated as required in 1) to 7). This record shall be available for inspection.

To ensure that training is uniform and of equivalent quality, training courses should reference the European Qualification Framework (EQF).

4.3 First aid and unintended needle-stick injury

All persons undertaking tattooing shall have received training in first aid measures relevant to the context of tattooing.

The tattooist shall provide documented evidence of being trained in such first aid. First aid training should be performed according to national regulations, where they exist.

First aid equipment shall be available and adequately stocked.

If the client has had an unintended needle stick injury (i.e. percutaneous exposure to a sharp contaminated with somone else's body fluid), they shall be advised and assisted to seek immediate medical advice.

Where the tattooist has a needle-stick injury, immediate action shall be taken because of the risk of infection with blood borne viruses (HIV, Hepatitis B and C).

The tattooist should comply with the instructions in Annex B following a needle-stick injury.

4.4 Vaccination

All tattooists should be vaccinated against Hepatitis B and records of all such vaccinations should be retained.

5 Facilities

5.1 General requirements for facilities

The facilities to be provided by the business owners/operators are detailed below including those to be provided at conventions and other non-permanent and temporary operations.

5.2 Requirements for tattooing premises

All areas shall be kept clean and uncluttered at all times.

The following shall apply to the premises:

— a documented cleaning programme in place for all areas and records maintained;

— all hard surfaces shall be in good repair and easily cleanable;

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— all areas shall be clean and free from extraneous items;

— sterile products shall be stored appropriately.

5.3 Requirements for tattooing area

Tattooing shall be carried out in a specific area of the premises separated from the other areas and clearly identified.

— The walls and floors shall be smooth, impervious, and easy to clean and disinfect.

— The construction, equipment and furnishings shall be suitable to ensure hygienic tattooing.

— The tattooing area shall be well ventilated and adequately lit.

— Work surfaces in the tattooing area shall be smooth, impervious and easy to clean and disinfect.

— A single use impervious barrier film/paper should be placed on the chair/couch/arm rest.

— The floor in the tattooing area shall not be carpeted.

The following waste containers shall be provided and clearly identified to facilitate separation of domestic and contaminated waste:

— a waste bin with hands-free opening for contaminated waste, where it is a national regulation requirement;

— an open waste bin lined with a clean plastic bag for general waste;

— a sharps container (see 5.4.3).

The work area shall be cleaned and disinfected prior to setting up for each client.

The following equipment shall be provided for hand hygiene:

— running water of drinking quality supplied from a tap with hands-free operation;

— liquid soap dispenser, preferably with hands-free operation;

— hygienic hand rub dispenser, preferably with hands-free operation;

— paper towel dispenser;

— bin for the disposal of paper towels.

Separate facilities shall be provided for:

— hand washing in the tattooing area;

— hand washing in the toilet facilities;

— dish washing, where necessary;

— cleaning of equipment and for the disposal of water used to clean reusable equipment. These shall not be the same facilities as used for hand washing.

The furniture provided shall be able to adequately support the client during the procedure. The client shall be physically supported whilst the procedure is carried out.

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The following shall not be permitted in the tattooing area:

— eating and drinking;

NOTE Except when necessary for the client's well-being.

— smoking, e-cigarettes and other electronic nicotine delivery systems;

— consumption of non-prescribed and illegal drugs or alcohol;

— animals, except guide dogs and companion dogs for special needs, (see national regulations).

5.4 Waste management

5.4.1 Waste associated risks

Tattooing generates biohazardous waste, which shall be segregated according to risk and disposal categories in accordance with national requirements.

The tattooist shall note the waste separation categories in Table 1.

Table 1 — Waste separation

	Contaminated waste		**Non-contaminated waste**
Waste container	Sharps container	Plastic waste bag in bin	Waste bin
Waste type	Sharps	Non-sharp waste with body fluid (including blood) contamination	Non-contaminated waste
Examples	Razors, blades, needles	Gloves, ink caps, single use tubes, compresses	Packaging, hand towels

5.4.2 Waste disposal process

Waste bags, fit for purpose, shall be used for waste disposal.

Contaminated waste from the work area shall be securely stored and disposed of in accordance with national requirements.

Stored contaminated waste shall not be accessible to unauthorized people and animals.

Waste generated during a tattooing session shall be disposed of as soon as possible into the appropriate waste bins, which shall be emptied at least daily. Waste bins shall not be allowed to overflow. It is important, not to touch the waste bin during a tattooing session due to the potential of cross-contamination.

The business owner/operator is responsible for monitoring the performance of staff and the waste disposal.

5.4.3 Sharps disposal

Sharps (e.g. needles) disposal containers compliant with EN ISO 23907-1 shall be used. The container shall close securely and should be disposed of according to national regulations.

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5.5 Conventions

All requirements in this document shall also apply to tattooing carried out at conventions.

The organizer of the convention shall ensure that every tattooist, including any tattooist visiting from other countries, is made fully aware of all relevant regulations and guidelines applicable in the country hosting the convention.

Each tattooist participating in a convention should ensure compliance with the national regulations of the host country regarding the safety of clients and employees.

The organizer shall be responsible for the provision of a safe tattooing environment to be used by the tattooist and communicate to visiting tattooists the facilities that will be provided at the convention.

Where, for practical reasons, the requirements of the hand-washing facilities for tattooists cannot be provided at a convention, the following variations may be used:

— At each tattooist's stand a hygienic hand rub shall be available.

— Easily accessible hand washing facilities shall be located separately from the toilets.

— The walking distance from any work area to the hand washing facilities shall be no further than 25 m and an accessible pathway shall be maintained.

— The water used shall be drinking water quality. The use of tanks for short-term storage of water is acceptable, i.e. not more than one day's supply.

Waste water shall not be disposed of in a hand-washing facility.

Sterilization shall not be undertaken on the convention site. Therefore reuseable sterile equipment shall be used once only.

Where carpet is already present at a convention, it shall be protected with an impervious covering.

The organizer shall retain details of the tattooists offering tattooing services at the convention and this should include: the tattooist's name, business name, business address and the registration and/or licence and training certificates of practising tattooist at the convention.

6 Cleaning, disinfection and sterilization of equipment and premises

6.1 General requirements for cleaning, disinfection and sterilization

There shall be a documented, regular cleaning and disinfection programme in operation.

All products selected for cleaning and disinfection shall be suitable for the purpose (including recommended compliance with any national regulations) and used in accordance with the manufacturer's instructions.

The instructions relating to dilution and contact time for all chemicals and disinfectants shall be adhered to by the business owner/operator and only the quantities required for immediate use should be prepared.

Chemical disinfection should only be used for the environment and non-invasive items. Chemical disinfectants are usually inactivated by organic matter and should only be used after cleaning has removed the majority of organic matter.

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