



Tattooing - Safe and hygienic practice

Services de tatouage - Pratiques sûres et exigences d'hygiène

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prEN 17169:2017 (E)

European foreword

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Introduction

This standard details evidence-based guidance on hygienic and safe tattoo practice to minimize risk of infection for both the client and the tattooist.

It is essential to minimise infection risks from tattooing to clients, tattooists and others working in tattoo premises by use of appropriate hygiene procedures. Anyone carrying out tattooing need to be responsible for their own, their clients' and others' safety in respect of the tattooing process.

It is essential to also apply relevant national regulations, where appropriate.

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prEN 17169:2017 (E)

1 Scope

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 374, *Protective gloves against dangerous chemicals and micro-organisms*

EN 455, *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, *Sharps injury protection — Requirements and test methods — Sharps containers (ISO 23907)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. [SIST EN 17169:2020](https://standards.iteh.ai/SIST/EN/17169/2020/cef6d39f3411/sist-en-17169-2020)

3.1

cleaning

removal of foreign materials from a surface

3.2

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]

3.3

single use

product intended to be used once and then discarded

[SOURCE: EN ISO 11810:2015, 3.18]

3.4**sterile**

free from viable microorganisms

[SOURCE: ISO/TS 11139:2006, 2.43]

3.5**sterilization**

validated process used to render product free from viable microorganisms

[SOURCE: ISO/TS 11139:2006, 2.47 – modified: Note 1 omitted]

3.6**aftercare**

care process following tattooing to assist optimal healing

3.7**steam sterilizer**

autoclave

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

3.8**connector cable**

clip cord

electrical cable connecting power supply and drive unit for tattooing

3.9**drive unit**

motor used to power tattoo apparatus

3.10**dry heat sterilization**

use of non-moist heat to achieve sterilization

3.11**grip**

textured surface cylinder connecting tube and tip intended to provide a secure grasp for the tattooist during the process of tattooing

3.12**hand hygiene**

process used to inactivate or remove acquired microbes on hands regardless of the resident skin flora

3.13**hygienic hand rub**

product (liquid, gel or foam) applied to hands and rubbed to dryness intended to inactivate acquired microorganisms regardless of the resident skin flora

3.14**ink cap**

plastic cap that holds tattoo ink

prEN 17169:2017 (E)**3.15****ink cap tray**

tray with recesses to hold a number of ink caps

3.16**no touch tap**

tap which can be operated without using hands

3.17**skin preparation**

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

3.18**sterilization container**

container that allows steam sterilization of the contents and protects that sterility afterwards whilst it remains unopened

EXAMPLE Pouches and boxes.

3.19**tattoo**

any procedure that penetrates the skin or mucous membrane for the purpose of insertion of colourants (pigments and dyes) to create a permanent or long-lasting design

3.20**tattoo machine**

DEPRECATED: tattoo gun

fully assembled device that produces reciprocal movement of a tattooing needle

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

3.21**tip**

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

3.22**tube**

hollow cylinder through which the needle bar passes

3.23**needle bar**

rod connecting tattoo machine and needle

3.24**ultrasonic cleaner**

device that cleans by immersion aided by ultrasonic energy

3.25**body fluids**

fluids such as blood, serum and other bodily 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.

3.26**disinfectant**

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

Note 1 to entry: A national registry and/or European Product Regulation might apply in your country.

3.27**disinfection**

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

3.28**sharps disposal container**

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

3.29**pre-treatment**

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

3.30**validation**

documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

[SOURCE: EN ISO 17664:2004, 2.11]

4 Responsibilities of the business owner**4.1 General**

Business owners shall be responsible for ensuring the necessary registrations and licenses required for the business are in place and copies of all relevant documents are available.

Business operators (employers) in the tattooing industry shall ensure that all staff are trained commensurate with their activities. Training may be provided by the business operators using documented procedures that address the activities of the business.

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

- 1) the basics of hygiene including personal safety as well as environmental hygiene such as cleaning and disinfection. Knowledge of sterilization of equipment; is required if the tattooist uses sterilization procedures;
- 2) the basics of microbiology and the study of relevant infection prevention;
- 3) the anatomy of the skin and basics of wound care, and contraindications;
- 4) the principals of occupational safety and health;
- 5) first aid;
- 6) an understanding of legal and other relevant requirements applicable to the business activities.

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

prEN 17169:2017 (E)**4.2 Training**

The curriculum shall be delivered to students over a minimum of 21 h.

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

The training shall include:

- the curriculum as specified in this document;
- one day of practical work; and
- an assessment in a training environment or by a peripatetic assessor.

A refresher course to reinforce and update previous training shall be undertaken at least every 5 years.

A record of staff training shall be retained and updated as required. This record shall be available for inspection.

If tattoo operators are sterilizing instruments, they shall receive training in knowledge and skills in the following:

- the basics of sterilization;
- all steps in the process of sterilization (see Clause 6).

The owners of a tattooing business should document, maintain and update a procedures manual to ensure that best practice is used in the premises.

The contents 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 premises (including all equipment and surfaces);
- waste management;
- after care procedures.

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

- the validation of the sterilization process;
- copies of autoclave maintenance details, etc.;
- the method of inspection of packing and seals, copies of sterilizer maintenance details;
- the storage practices and facilities for sterile packs.

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