

Tatovering – Sikker og hygiejnisk praksis

Tattooing – Safe and hygienic practice

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Tattooing - Safe and hygienic practice

Tatouage - Bonnes pratiques d'hygiène et de salubrité

Tätowieren - Sichere und hygienische Praxis

This European Standard was approved by CEN on 9 October 2019.

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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of an identical text or by endorsement, at the latest by July 2020, and conflicting national standards shall be withdrawn at the latest by July 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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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.

Tattooing – Safe and hygienic practice

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

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

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

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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

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]

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](#).

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 someone 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;
- 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;

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- 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.

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.

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.

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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.

6.2 Environmental cleaning and disinfection

The tattooing area shall be kept clean and tidy and procedures shall be in place for routine cleaning.

Tattoo couches shall be cleaned and disinfected after each client.

Working surfaces shall be cleaned and disinfected after each client.

Floors, working surfaces, chairs and washing facilities shall be cleaned thoroughly at the end of each day.

Surfaces which may have been in direct or indirect contact with a client's body fluids shall be cleaned and disinfected immediately with an appropriate disinfectant.

6.3 Cleaning and disinfection of equipment

6.3.1 General requirements for cleaning, disinfection and sterilization of equipment

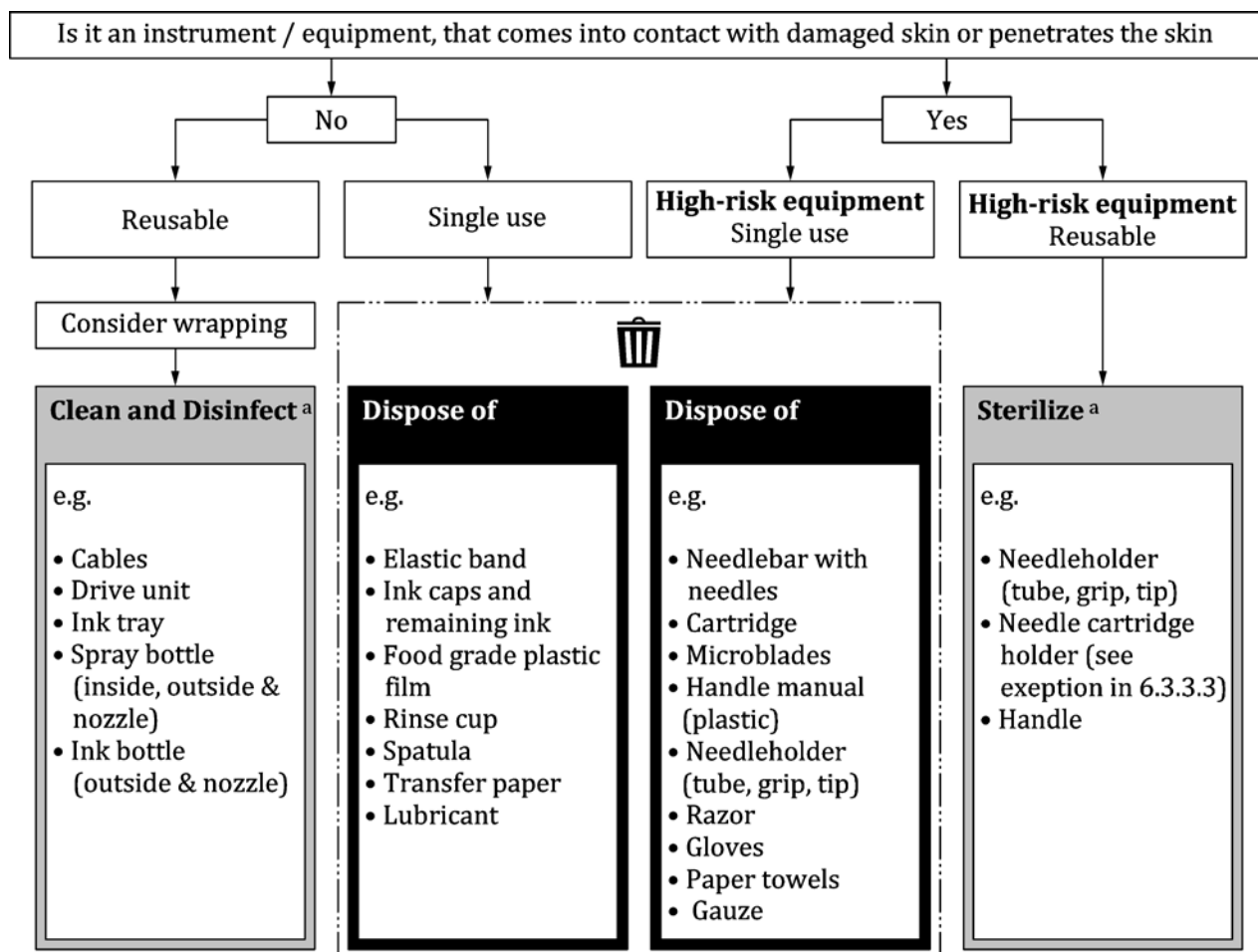
Cleaning of equipment shall be carried out as soon as possible after each client.

All items of equipment including cable, drive unit and wash bottle, which are to be reused and cannot be sterilized shall be protected from contamination, e.g. by using single use plastic sleeves and films.

Persons in contact with contaminated items shall wear gloves and should also wear an apron and eye protection, when dealing with contaminated equipment or material e.g. cleaning, tattooing, etc.

[Figure 1](#) provides a flow diagram for disposal, cleaning, disinfecting and sterilizing.

In some countries additional disinfection steps may be required.



Key

a Disinfection and sterilization involve all preceding processes.

NOTE — It is essential to use [Figure 1](#) together with the text of [Clause 6](#).

Figure 1 — Flow diagram for cleaning, disinfecting and sterilizing

6.3.2 Equipment for single use

Single use sterile needles or single use sterile needle cartridges shall be used.

Single use sterile needle holders (tube, grip and tip) or needle cartridge holders (grip, or grip and tube) with sterile needle cartridges shall be obtained from a suitable supplier who can demonstrate that the production process for the sterile equipment has been validated.

Single use equipment shall not be used if the packaging or equipment is damaged or past its use-by date.

6.3.3 Treatment of equipment for reuse

6.3.3.1 General

The cleaning and disinfection and, where used, sterilization facility shall be specifically identified within tattooing premises either as a separate room or a dedicated part of the treatment room.

When carried out in a dedicated part of the tattooing area it may be done without the presence of clients.

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Items to be prepared for reuse shall flow along a defined routine procedure from dirty (i.e. used and contaminated), through cleaning (which should have both a manual and an ultrasonic stage, see [Annex C](#)), through sterilization and into a phase of clean storage prior to return to use.

6.3.3.2 Pre-treatment

Contamination becomes more difficult to remove if it is allowed to dry. If equipment cannot be cleaned immediately after use, it shall be kept moist until cleaning, e.g. immersed in a pre-treatment bath or otherwise.

6.3.3.3 Cleaning

Equipment shall be disassembled before cleaning. Cleaning shall be carried out in a wash facility dedicated to equipment cleaning and not one shared with other functions (handwashing, eating utensil washing etc.). Water below 40 °C shall be used, as water at a higher temperature can coagulate proteins onto the equipment making it difficult to remove.

Needle holders and needle cartridge holders which are not single use items shall be taken apart prior to cleaning and shall be placed in a bath containing a cleaning agent. The cleaning agent shall be used in accordance with the manufacturer's instructions and disposed of at the end of each working day. The bath with equipment and cleaning agent should be placed in a safe, accessible space that will provide protection from falling over or spillage. Before any further processing, the pre-treated needle holder shall be rinsed with water of drinking water quality.

Utensils used for equipment cleaning shall be used only for that purpose and shall be fit for purpose (e.g. bristles on brushes in good order). The person responsible for cleaning shall ensure that cleaning takes place under the surface of the cleaning solution to minimize the potential of splashing.

The cleaning shall be followed by rinsing to remove any residue of cleaning agent.

Cleaning of difficult to reach surfaces should be carried out with additional utensils (e.g. brush).

A visual inspection using adequate lighting shall be carried out to ensure that all equipment is clean with particular attention to hollow spaces, edges and corners to ensure that all contaminations have been removed.

Where on inspection the equipment is not clean, the cleaning and inspection process shall be repeated until the equipment is clean.

If inspection shows any equipment having signs of wear e.g. rust or surface deterioration, it shall be discarded.

Where a needle cartridge is sealed to effectively prevent liquid transfer into the needle cartridge holder, such that there is no ingress of body fluids, the needle cartridge holder is not regarded as high-risk equipment. The needle cartridge holder shall be made safe for reuse by treatment with a suitable chemical disinfectant in accordance with the manufacturer's instructions. It shall be the responsibility of the tattooist to obtain and retain documented proof from the supplier that the needle cartridge in use is effectively sealed.

Where a cartridge without a physical barrier is used, a sterilizable or single use cartridge holder shall be used.

To ensure that a safely sealed product is used, the following shall be carried out:

- the supplier shall be asked for cartridges with a physical barrier;
- the labelling shall be checked to confirm that a physical barrier is provided;
- each cartridge type shall be tested by filling one cartridge sample with fluid (e.g. tattoo ink) and operating the back-end plunger while the tip is in upright position for at least 50 times to look for signs of leakage through the plunger.

6.3.3.4 Disinfection

Equipment that does not require sterilization shall be cleaned and disinfected.

Equipment to be disinfected by immersion shall be disinfected using a suitable disinfectant in accordance with the manufacturer's instructions.

Equipment to be disinfected (e.g. cable, driver unit, wash bottle) shall be protected with a single use cover, if possible and the cover shall be removed after the tattooing process. After unwrapping the equipment shall be cleaned (wiped) and disinfected.

Fixed wrapped equipment, such as the drive unit, cables and power supply, shall be unwrapped and wiped clean and disinfected immediately following use.

6.3.3.5 Sterilization

High-risk equipment according to [Figure 1](#) shall be sterilized.

The needle shall be sterile before starting the tattooing process. Needle holders with a lumen shall be sterile if the sterile needle passes through (e.g. tip, tube).

In addition to the single use sterile needle, all parts of the tattooing machine, which may have contact with the sterile needle during assembly of the machine, shall be sterile.

Where high risk equipment is to be reused and is sent offsite for disinfection and sterilization, the reusable needle holders and/or needle cartridge holders shall be conveyed in a transport box which is robust and leak resistant, and the contents kept moist to prevent the equipment drying out in transit.

6.4 Sterilization process

6.4.1 General requirements for the sterilization process

Sterilizers shall only be used by those trained in their correct operation. Sterilizers shall be operated according to the sterilizer manufacturer's instructions.

A validated sterilization process shall be used which shall at least include sterilization and packaging for maintenance of sterility during transportation and storage which is compatible with the instruments to be sterilized.

Steam sterilization is currently considered to be the most suitable method for the sterilization of tattoo equipment.

The method described in [Annex E](#), should be used for packing and sterilizing instruments.

Where sterilization is carried out away from the tattooist's premises or by a third party, the requirements for performing the sterilization shall be applied, both on the part of the sterilization device manufacturer and the manufacturer of the products to be sterilized.

NOTE — Information on the management of subcontracted sterilization is given in [Annex D](#).

6.4.2 Requirements for steam sterilizers

A steam sterilizer shall be used for all sterilization as this type of equipment will monitor each sterilization cycle and produce a record (e.g. printout) of the cycle parameters, particularly the temperatures attained throughout the sterilizing phase and the times of those temperature readings. If an existing steam sterilizer does not conform to [EN 13060](#), any subsequent replacement steam sterilizer shall conform to this standard.

If the current sterilizer does not conform to [EN 13060](#) and cannot produce a record of cycle parameters, equivalent records shall be produced by observation during the first cycle of the day when the sterilizer is in operation. If a steam sterilizer is incapable of providing these data, it shall not be used.

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The steam sterilizer shall be examined and tested annually according to [EN ISO 17665-1](#) by an external company in accordance with the manufacturer's instructions.

Sterilization processes shall be validated and maintained by technicians specifically trained to do so according to a schedule provided by the manufacturer of the sterilizer. In addition, periodic testing shall be included according to any national requirements. Records of validation and maintenance shall be retained.

When an existing sterilization unit is replaced or an additional unit is acquired, the replacement/additional unit shall be a steam sterilizer complying with [EN 13060](#) (e.g. class B or class S according to national regulation). When opening new tattooing facilities where sterilization on site is planned, steam sterilizers class B or class S complying with [EN 13060](#) shall be used.

NOTE 1 — The change of colour of the chemo-indicator of the pouches will indicate that the item has been subject to the sterilization process, but this does not confirm that effective sterilization has taken place.

NOTE 2 — Opened sterile materials can become contaminated with microorganisms.

6.4.3 Packaging to maintain product sterility

The packaging used shall be suitable for the type of sterilization in use, e.g. see [EN 868-8](#).

If sterilized products are not used immediately after sterilization the packaging (pouch) used shall be suitable to maintain sterility.

A separate pouch should be used either for individual items or for a set of disassembled items that are intended to be used for a single procedure. The items shall be sterilized while disassembled in the pouch.

All sterile instrument packs which have been opened but not used shall be re-packed and then re-sterilized.

Pouches shall conform to [EN ISO 11607-1](#) and the instructions of the pouch manufacturers shall be followed by the business owner/operator. Further information on the method for packing and sterilizing instruments is given in [Annex E](#).

The pouches shall be closed and sealed before sterilizing by, e.g.:

- using self-sealing pouches;
- heat sealing;
- sterilization tape.

6.4.4 Post sterilization inspection and storage

After sterilization has been completed the operator shall ensure that it has been effective and that the pouches are intact.

Wrapped items shall be stored to ensure that the wrapping remains intact and dry. The sterilization date and the batch number shall be recorded e.g. on the peel-off edge.

NOTE — A sticker, indelible stamp or marker pen that will not damage the packaging are suitable for writing information on the packaging.

The sterilized equipment shall be stored protected from dust and in dry conditions, e.g. boxes, drawers, cabinets. All sterilized equipment should be used on a first-in, first-out basis. Instruments that have been sterilized within the tattooing premises should be used within six months.

Packages shall be inspected before use and, if damaged or containing moisture, the contents shall be deemed to be not sterile and unfit for use.

7 Tattooing process

7.1 Interaction with the client

Prior to receiving a tattoo, the client shall be provided with a verbal and written statement of the procedure, risks and possible complications. The tattooist shall obtain from the client a signed informed consent form. Information on the tattoo ink shall be included in the client consent form. [Annex F](#) provides an example of a consent form, which includes an attachment that is a non-exhaustive list of examples. This list can be adopted or adapted.

The tattooist shall provide a copy of the signed consent form to the client and retain a copy on file (e.g. in accordance with national regulations where they exist).

7.2 Client suitability

Where a client requests a tattoo, the tattooist should comply with national regulations when providing the service.

In the absence of specific regulations, the following shall apply:

- no tattoos to be provided to individuals under the age of 16;
- tattoos may be provided to individuals under the age of 18, where the consent has been provided in person to the tattooist by the parent or legal guardian.

Tattoos shall not be provided to:

- individuals showing signs of impaired judgements e.g. due to alcohol consumption or drug use;
- women who have indicated they are pregnant or breastfeeding.

Tattooists should inform the client about the risks of tattooing especially if the client has one of the following conditions:

- any known allergies (including latex allergy);
- diabetes;
- haemophilia or other clotting disorders;
- sarcoidosis;
- any skin disease;
- any autoimmune diseases;
- conditions that result in a compromised immune system;
- cardiac and vascular disorders;
- scar tissue including keloid scars;
- areas of skin that appear damaged or abnormal, including moles and birth marks.

This list can be adopted or adapted.

The tattooist shall not apply any local anaesthetic and shall not tattoo the same area until healing is complete.

Where necessary, the client should be advised by the tattooist to seek medical advice.

7.3 Aftercare information

The tattooist shall provide the client with verbal and written information concerning tattoo aftercare. This shall include information on the known potential complications associated with the particular procedure, the effect of inadequate care and strong sunlight. The client shall be advised not to touch the tattoo whilst healing and when contact is necessary to ensure that hands are washed before and after. The tattooist should be available to advise any client with problems during regular opening hours of the studio. If despite these precautions abnormal signs (see [G.4.3](#)) occur, the client shall be referred to a physician.

The tattooist shall explain to the client:

- the importance of good hygiene;
- any known complication associated with the particular procedure.

The tattooist shall provide information on activities to be avoided during the healing period:

- sauna, sun bed, direct sunlight;
- swimming.

That aftercare advice has been provided shall be recorded by the client. For example the consent form can include a tick box, signature or similar indicator to record that aftercare advice has been explained at the time that the consent form was signed by the client.

The tattooist shall record and retain information on the inks used to apply the tattoo (see [7.8](#)).

Where the client informs the tattooist of a concern or problem, the tattooist should keep records of any action taken and advice given.

For further information on generic wound management see [Annex G](#).

7.4 Hand hygiene

Hand hygiene shall be performed immediately:

- before and after each client;
- after contact with body fluids;
- before putting gloves on and after the removal of gloves;
- after using a tissue or blowing the nose;
- after any activity or contact with a client's surroundings that could result in hand contamination.

How to carry out hand hygiene is detailed in [Annex H](#).

Artificial nails, nail polish and all hand and wrist jewellery including watches shall be removed before tattooing. Wearing a plain wedding band is acceptable if permitted by national requirements.

Any visible wounds shall be covered with a waterproof dressing.

Hygienic hand rubs shall conform to [EN 1500](#) or should be accepted by national registry and/or European Product Regulation.

Tattooists shall have a nail length compatible with glove use.

NOTE — For hand washing any detergent or soap acceptable to the user can be used. Antimicrobial soaps do not provide additional protection.

7.5 Personal protective equipment (PPE)

7.5.1 Gloves

The gloves to be worn by tattooists shall be single use gloves complying with the [EN 455 series](#) and the [EN 374 series](#). Hands shall be washed or disinfected, see national regulations where they exist, before putting on gloves and following the removal of gloves.

Gloves shall be worn when:

- carrying out tattooing;
- in contact with sterile sites and non-intact skin or mucous membranes;
- carrying out activities that have been assessed as a risk of exposure to body fluids;
- exposed to sharp or contaminated instruments.

Using latex-free gloves avoids exposure to latex allergens and is recommended as the standard glove to be used in tattooing.

As a minimum, the tattooist shall change gloves in the following circumstances:

- following cleaning of the work area;
- for each new client;
- if tattooing is interrupted for any reason (e.g. phone call, coffee break, etc.);
- for provision of aftercare treatment to the client.

The tattooist shall remove the gloves when tattooing is finished and dispose of them in an appropriate manner.

7.5.2 Other PPE

All outer clothing shall be clean and a clean apron should be worn to prevent the risk of contamination from outer clothes. Aprons shall be changed between clients or when leaving the work area.

Where splashing to the face is a risk, protection for the face, including the eyes, should be used. This can be a mask, glasses or a visor.

Where the lower arm of the tattooist may come into contact with the area being tattooed, the tattooist should reduce the risk of exposure to contamination by wearing single use plastic sleeves. Clothing on the arms should not cover below the elbow.

7.6 Tattooing area

The tattooing area shall be prepared before the service is provided by:

- cleaning and disinfecting the work area at the beginning of the work day;
- cleaning and disinfecting the work area between each client;
- protecting the disinfected area with waterproof covering;
- setting out sterile ink caps;
- dispensing ink into the caps ensuring the ink bottle does not make contact with the cap;
- replacing used ink caps by new sterile caps, as they shall not be refilled;
- setting out rinsing water of drinking water quality in a wash bottle;

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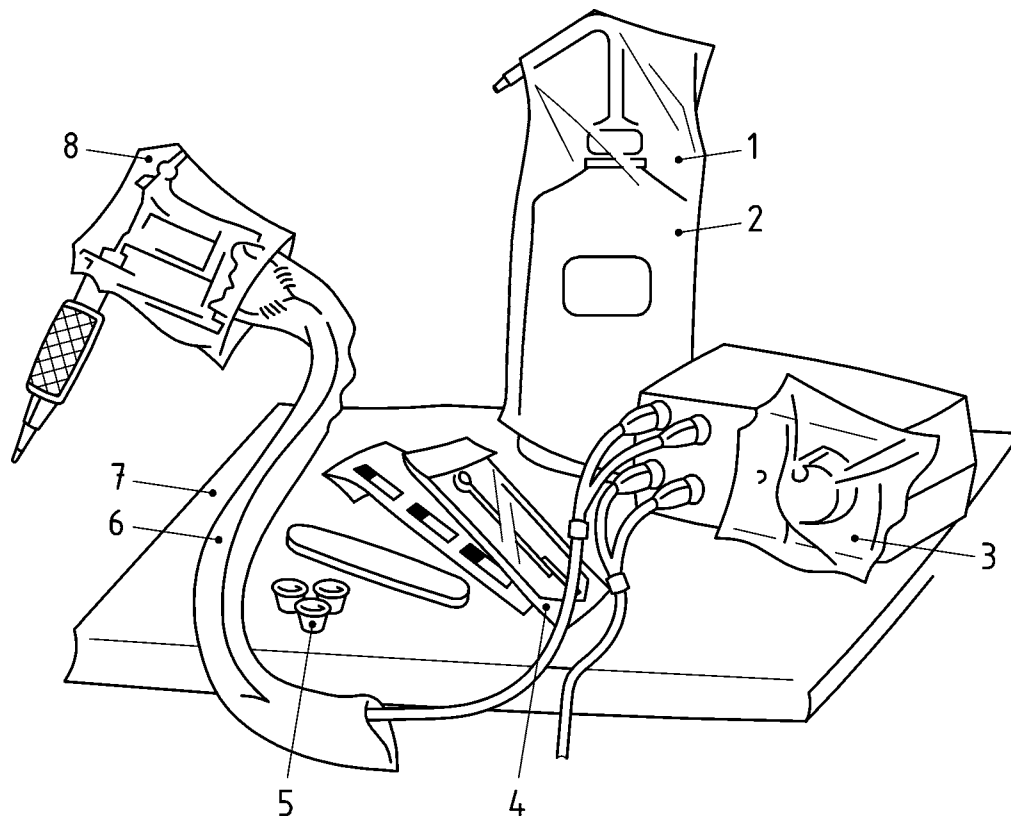
— ensuring the items as illustrated in [Figure 2](#) are within reach of the work area.

The wash bottle shall be labelled with the ingredients, be clean, washable and its contents shall be changed daily. Wash bottles shall be emptied at the end of the working day, rinsed, dried and stored in a dry area.

To reduce the risk of biofilm formation, wash bottles shall either be:

- disposed of after a week of use; or
- boiled for one minute or disinfected by atmospheric pressure steam, such as baby bottle steamer; or
- steam sterilized if compatible.

All bags shall be single use.



Key

- 1 bottle bag
- 2 wash bottle labelled
- 3 power supply protection
- 4 needles, tubes, spatula
- 5 ink caps
- 6 tattoo machine cable protection
- 7 waterproof cover
- 8 tattoo machine bag

Figure 2 — Typical layout of a tattoo working area

7.7 Equipment

The tattoo drive unit shall be cleaned, disinfected and covered prior to use for each client.

The connector cable shall be protected with a single use covering for each client.

The drive unit should be protected with a single use covering for each client.

The drive unit and connector cable shall be cleaned and disinfected immediately after the completion of each client session.

Where a reusable ink cap holder is used to mount the ink caps, it shall be disinfected before each use.

Where used, fitted rubber bands, grommets and top hats should be replaced between clients.

Single use sterile equipment (tips, grips, tubes and needle cartridges) that have been sterilized by a validated process, should be used for each client where available.

Tattoo or permanent make-up devices are available in different types. These types are usually electrically powered, but can also be manually operated.

The different devices are available as single use or as reusable items, but can also have some parts as single use within a reusable system.

Figure 3 provides an overview of tattoo devices.

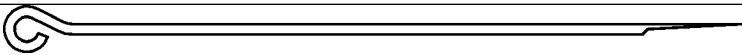


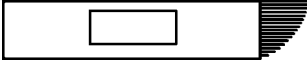

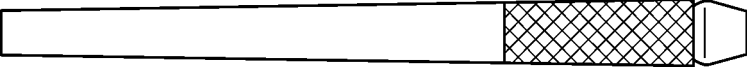



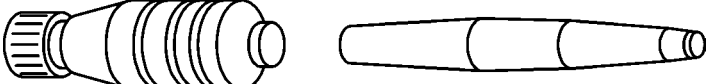
Item	Material
	needle bar with needle
	needle bar with needle
	needle cartridge with safety system
	micro-blade
	handle manual (plastic)
	handle manual (metal)
	tube (metal or plastic)
	tip (metal or plastic)
	grip (metal or plastic)
	needle cartridge holder (powered handle)

Figure 3 — Tattoo devices

7.8 Tattoo inks

The tattooist should check that the ink intended for use is not prohibited by national legislation and is correctly labelled, with the following information:

- intended use of the mixture as a 'tattoo ink';

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- a reference number to uniquely identify the batch;
- name and address of manufacturer/supplier;
- expiry date;
- shelf life after opening/PAO (period after opening);
- name of all substances present in the tattoo ink;
- guarantee of sterility;
- storage conditions;
- any relevant instructions for use.

Ink bottles shall be stored:

- in a closed, clean, dry area; and
- away from sources of heat, direct sunlight and public access.

The opening date shall be recorded on each ink bottle.

The batch and lot number of ink used for each client shall be recorded on the client record.

The information provided on bottles of ink used shall be made available to the client. The client shall be advised to retain the information.

Ink shall be mixed if necessary, immediately prior to use. Where inks require dilution this shall be done using sterile water taken from a single use vial or a sterile diluent and used in accordance with the manufacturer's instructions.

The ink bottles shall be closed immediately after use and the nozzle shall be cleaned using a tissue, either dry or with a disinfectant added.

For inks and related products a stock control system shall be in place e.g. using the use-before dates.

Any damaged ink bottles, dried out and expired inks shall not be used and shall be properly disposed of.

7.9 Lubricant, shaver, spatula, paper towels, ink caps and skin cleansing

Suitable lubricant intended for use for tattooing (preferably petroleum jelly to pharmacopoeia standards), shavers, spatulas and paper towels shall be stored in closed containers away from the work area.

The tattooist shall:

- wear single use gloves when handling the shaver, ink caps and spatula;
- use a single use shaver;
- apply and remove surplus lubricant with a single use spatula, or a spatula which is capable of being sterilized and is sterilized between clients. Note the date of opening on the jar. The maximum period of use after opening is six months;
- select the required quantity of paper towels for the procedure;
- dispose of all used paper towels in an appropriate waste bin.

Only sterile ink caps shall be used.

7.10 Skin preparation

The tattooist shall disinfect the skin to be tattooed before starting the procedure.

Disinfectants shall be used according to the manufacturer's instructions including the contact time.

The tattooist shall prepare the skin before starting the procedure as follows:

- Ensure the area to be tattooed is clean and free from signs of infection, allergy, dermatitis, wounds, rashes and cuts.
- Thoroughly wash and clean the area to be tattooed and surrounding areas.
- Shave the area, where appropriate, immediately prior to starting the procedure, with a single use safety razor.
- Wipe the area with a skin disinfectant while removing any loose hair from the area.
- If the template is painted freehand, use single use or sterilizable markers.
- Apply any prepared stencils.

Disinfectant suitable for mucous membrane or periorcular use shall be used where the area to be tattooed includes mucous membranes (e.g. oral and genital tattoos) or is close to the eyes.

7.11 Rinsing the needle while tattooing

When changing inks during tattooing and if the needle needs to be rinsed, this shall be carried out in water in a single use container which may be held within an ultrasonic cleaner.

For each client, a new single use container shall be used and shall be:

- rinsed with a suitable disinfectant;
- filled with sterile water or, if not available, water of drinking water quality.

After the tattooing is completed the contents of the container shall be poured down the washing facility used for cleaning dirty equipment and the container disposed of as waste.

7.12 Procedure

a) Before the procedure:

- Ensure the procedure is fully explained to the client and obtain their written consent.
- Place the single use barrier film/paper on the chair/couch/arm rest and adjust as required appropriate to the procedure to be undertaken.
- Thoroughly wash hands using running water and liquid soap, rinse and dry carefully using a suitable method of hand-drying, as per the procedure in [Annex H](#).
- Put on a pair of single use gloves according to [7.5.1](#) (see [EN 455 series](#) and [EN 374 series](#)) and a clean apron.
- Ensure all items required are within easy reach of the clean work area. This is to avoid interruptions which can lead to increased risk of contamination.
- Assemble the tube, tip and grip, in front of the client, open the single use needle bar with needle attached or assemble components of non-electrical devices in an equivalent way and insert into the tube. Assemble the tattooing machine(s) and place on the instrument tray ready for use. Assemble the cartridge system.

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- Suitable lubricant intended for use for tattooing (preferably petroleum jelly to pharmacopeia standards) shall be decanted at the working area using a single-use spatula. A single-use device or gloved hand shall be used to apply the lubricant to the skin.
- Choose the required inks and dispense same into sterile single use ink caps ensuring sufficient quantity to complete the procedure.
- b) During the procedure:
 - Stencils shall only be used on one client due to the high risk of cross-contamination. Solutions used for transfer should be used sparingly.
 - During tattooing use ample single use paper towels.
 - The tattoo shall only be touched when necessary with equipment and gloved hands.
 - If the tattooist's skin is pierced by the needle before or during the procedure, the needle shall be changed immediately before proceeding further on the client.
- c) After the procedure:
 - Clean surfaces which may have been in direct or indirect contact with the client's body fluids and disinfect immediately with an appropriate disinfectant.
 - Place all contaminated instruments into a container and move this to the cleaning area/zone. Refer to [6.3](#) for detailed information on the cleaning of reusable instruments.
 - Discard any needles into the sharps container immediately following use.
 - For information on waste management see [5.4](#).
 - Clean the container used to collect used equipment.
 - Remove the single use barrier film/paper from the client chair/couch/arm rest.
 - Remove gloves and perform hand hygiene.
 - Verbal and written instructions on the aftercare of the tattooed site shall be given to the client, see [7.3](#).
 - Aftercare recommendations are given in [Annex G](#).
 - The work area shall be disinfected using single use gloves. Wipe down the liquid dispensing bottle(s) used. Wipe down the tattoo machine, tattoo machine cable and the power supply with disinfectant.
 - Receive payment and store money outside the work area and wash hands after handling money or other payment systems.

Annex A **(informative)**

Basic framework for training and qualification on infection prevention and control

A.1 General

The objective of the training is to provide a comprehensive knowledge of the content of this standard, together with skills and competencies to put it into practise. The indicated level of courses should be at least at EQF level 4. The desired learning outcomes are described below.

NOTE — There are no educational prerequisites to start the courses under EQF.

A.2 Structure of the skin

- a) Receivers of training will be able to differentiate the different layers of the skin and the underlying structures:
 - epidermis;
 - dermis;
 - subcutaneous tissue.
- b) Receivers of training will be able to describe:
 - the principles of tattooing: application of a colourant on or in the skin;
 - different types of tattooing (e.g. regular tattooing, micro blading, permanent makeup);
 - where the tattoo pigment is located and what happens with the applied ink;
 - the consequences of misapplication and how deep application will result in blurring and fanning of the colourant.
- c) Receivers of training will be able to identify the different stages of wound healing.
- d) Receivers of training will be able to describe the function of the skin (how it acts as a barrier against negative influences of the environment) and to recognize the following, and understand the role of:
 - chemical defence (and the effect of soap);
 - thermoregulation;
 - UV protection (melanin);
 - mechanical barrier against aggressors.

A.3 Microbiology and the skin

Receivers of training will have knowledge on:

- Normal skin flora: residents (e.g. *Staphylococcus epidermidis*);

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- Abnormal skin flora:
 - resident (e.g. *S. aureus*/MRSA) explaining risks of MRSA carriers;
 - transient (bacteria, e.g. *pseudomonas*, *mycobacteria*; yeasts and fungi; and viruses, e.g. herpes, molluscum and warts).

A.4 Transmission of infection

- a) Receivers of training will be able to describe the transmission sources, including:
 - skin, body fluids, unintended needle-stick injury (specific information on Hepatitis B, Hepatitis C, and HIV);
 - external factors, e.g. tap water.
- b) Receivers of training will be able to describe the following transmission routes:
 - client ↔ client;
 - material/procedure ↔ client;
 - tattooist ↔ client.
- c) Receivers of training will have knowledge on:
 - people at risk (diabetics etc.);
 - preventive measures (hand hygiene, gloves, disinfection etc.);
 - characteristics of disinfectants.

A.5 Clinical presentation of skin conditions

Receivers of training should be aware of indications of common bacterial and viral infections and allergies.

Receivers of training should be able to recognize:

- normal healing;
- wound infection; and
- early signs of blood poisoning.

A.6 Inks

Receivers of training will have knowledge on:

- composition (basics: colourants, auxiliary ingredients, impurities from the production process);
- regulation; CoE ResAp. (2008)1;
- requirements (labelling, sterility, storage);
- practice: interpretation of the ink label, e.g. PAO (period after opening);
- risks (contamination, toxicity, allergy); with special attention for diluents and mixtures;
- side effects due to the inks (e.g. allergy to red etc.).

A.7 Occupational safety

Receivers of training will be aware of:

- body fluid exposure;
- Hepatitis B, C: risk of transmission, signs and symptoms;
- Hepatitis B vaccinations/evaluation of immunity;
- HIV: risk of transmission, signs and symptoms.

Receivers of training will be able to put into practice:

- the preventive effect of hand hygiene and gloves and when and how to use gloves;
- personal hygiene and gloves removal.

A.8 Client information / selection / exclusion

- a) Receivers of training should be able to explain the informed consent form.
- b) Receivers of training should be able to evaluate client suitability based on the following:
 - age;
 - do's and don'ts;
 - specific information related to specific conditions (diabetes, scars etc.).
- b) Receivers of training should be able to explain why some areas of the body should not be tattooed (see also in [F.2](#)).
- c) Receivers of training should be able to explain aftercare information (advantages and disadvantages of different methods).

A.9 Legal aspects

Receivers of training should have knowledge on the law and standards applying to the procedure, relevant hygiene regulations, certification and registration where applicable.

A.10 Work premises

Receivers of training should be able to ensure that the conditions as described in this standard are met for the following areas:

- requirements for tattooing premises (see [5.2](#));
- requirements for tattooing area (see [5.3](#));
- conventions (see [5.5](#)).

A.11 Waste management

Receivers of training should be able to outline:

- waste associated risks (see [5.4.1](#));
- waste disposal process (see [5.4.2](#));

- sharps disposal (see [5.4.3](#)).

A.12 Cleaning, disinfection and sterilization

- a) Receivers of training should have knowledge and skills in the following areas:
- basics of cleaning, disinfection and sterilization with all steps of the relevant procedures, including documentation, maintenance and validation;
 - specific training and knowledge of the devices they are using to perform sterilization.
- b) Receivers of training should be able to describe the cleaning, disinfecting and sterilization techniques in detail.
- c) Receivers of training should be able to execute the method for packing and cleaning, disinfection, sterilizing and maintenance of a “first in, first out” (FIFO) logbook.

A.13 Safe practice for tattooing

Receivers of training should be able to reproduce the different steps of the hygienic tattooing process:

- performance of hand hygiene (see [7.4](#));
- application of personal protective equipment (see [7.5](#)) including the use of gloves (see [7.5.1](#)) and other protective equipment (see [7.5.2](#)) like apron, sleeves and mask;
- preparation of a tattooing area (see [7.6](#));
- handling of tattoo inks (see [7.8](#)) including traceability which entails: registering the brand, colour, batch and lot numbers of the inks on the client file/informed consent form;
- handling of other materials (see [7.9](#)) e.g. lubrication;
- skin preparation (see [7.10](#)).

Annex B **(informative)**

Body fluid exposure

This emergency procedure should be followed immediately on occurrence or on the realization or discovery of exposure:

- 1) Stop ongoing tattooing.
- 2) Remove gloves.
- 3) Do not suck the wound.
- 4) Wash the wound with mild liquid soap under running warm water thoroughly.
- 5) Do not use a scrubbing brush.
- 6) If eyes, nasal cavity or conjunctiva are involved, wash immediately with water for (5 to 10) min (use tap water, or sterile water if available).
- 7) If the mouth is contaminated, rinse thoroughly with tap water.
- 8) Any cuts/punctures should be covered with a waterproof plaster.
- 9) Where there is considerable contamination of unbroken skin, remove contaminated clothing and wash all affected areas with copious amounts of water.

Medical advice should be sought at the local Emergency Department because prophylactic treatment (if required) ideally needs to be given within one hour and no later than 72 h of the incident. The quickest response is vital to help enable the risk assessment process.

Ensure that the business owner/operator is informed immediately of the incident and that the incident is recorded in detail.

The person who has received the injury should complete an incident form as per local guidelines.

NOTE 1 — Further information can be found in WHO/ILO guidelines and 2010/32/EU, see Bibliography.

NOTE 2 — Other national requirements can apply where they exist.

Annex C **(informative)**

Ultrasonic cleaning

Care should be taken not to create sonic shadows by ensuring that all surfaces of instruments are fully immersed and contact with the liquid is not hindered by air bubbles. Hollow objects should be flushed and filled with liquid agent avoiding any air bubbles.

It is important to avoid high temperatures during the ultrasonic process because blood proteins may adhere to the instruments and may not be fully removed during subsequent cleaning. For this reason while it is possible to use heaters the liquid should not be above 40 °C.

Ultrasonic cleaning equipment should be located in the sterilization area.

Instruments that should be disinfected or sterilized should first be cleaned in an ultrasonic cleaning bath. Cleaning these instruments only by hand is not adequate.

- If ultrasonic cleaning is not immediate and a full ultrasound bath is not used to store equipment after use, equipment should be stored moist in a soaking tray. Dried blood and other deposits are difficult to remove in an ultrasonic cleaning bath.
- Use a cleaning agent as recommended by the manufacturer or a cleaning agent that is suitable for ultrasonic cleaning. To determine whether it is suitable, read the manufacturer's instructions included with the cleaning agent.
- If the ultrasonic cleaning bath is on, do not put your hands in the bath as this may result in cell damage.
- When using ultrasonic cleaning, follow the method described below.

Method for ultrasonic cleaning

- 1) Turn on the ultrasonic cleaning bath approximately ten minutes before starting to clean, to enable the tap water to de-gas. The gasses that are naturally dissolved in water will diminish the cleaning effect.
- 2) Put on gloves.
- 3) Remove the perforated tray with the instruments from the soaking tray.
- 4) Check the instruments for damage and rust. Dispose of damaged or rusty instruments.
- 5) Rinse and if necessary brush the instruments while submerged in the water to avoid splashing.
- 6) Disassemble instruments that are made of multiple components.
- 7) Clean the inside of hollow instruments using a pipe cleaner, an interdental brush (for the tip of the tube) or cotton buds. The diameter of the bristles of the lumen brush or interdental brush used should be less than the diameter of the instrument.
- 8) Place the complete instruments and the separate components in a perforated tray.
- 9) Remove and dispose of the gloves and perform hand hygiene.
- 10) Dissolve the ultrasonic cleaning agent to the correct concentration in accordance with the manufacturer's instructions. Never use a higher concentrate of ultrasonic cleaning agent than specified in the instructions as this will reduce its effectiveness.

- 11) Ensure enough cleaning agent is prepared such that the instruments can be fully submerged in the liquid.
- 12) Place the perforated tray with the instruments in the bath.
- 13) Close the lid to prevent the dispersal of aerosols. These are small particles of dust or liquid that are generated by the vibrations and may be contaminated with pathogens.
- 14) Set the appropriate cleaning duration as specified in the instructions. Four minutes is usually sufficient.
- 15) Do not allow the liquid in the ultrasonic cleaning bath to exceed 40 °C.
- 16) Remove the perforated tray from the bath and rinse the instruments in water.
- 17) Dry the instruments with a clean towel, tissue or kitchen roll. They are now ready to be sterilized.
- 18) At least at the end of the working day, the ultrasonic cleaner tank should be emptied, rinsed with water to remove solution residue, disinfected and allowed to dry (e.g. overnight) before being refilled with fresh solution.

Items with complex surfaces may require subsequent additional cleaning in an ultrasonic water bath (ultrasound creates strong microcurrents in water by a process known as “cavitation” and is very effective at removing soiling from otherwise hidden crevices). Ultrasonic water baths should be used and maintained according to the manufacturer’s instructions.

Annex D **(normative)**

Processes for subcontracted sterilization

Where sterilization is subcontracted, the used instruments shall be transported in a moist condition. The following shall be adhered to when sending instruments for subcontracted sterilization:

- Use a container that can be thoroughly cleaned and is sealable and leak proof.
- Place the perforated tray with the rinsed instruments in the container.
- Seal the container during transport.
- Separate clean and contaminated material containers during transport.
- The tattooist shall agree a contract with the sterilization service provider and retain this on the premises at all times.
- The contract for the sterilization service shall include but is not limited to:
 - a statement confirming that the sterilization will be carried out in accordance with the requirements of this document;
 - a log book which shall be retained by the sterilization service provider.
- The tattooist shall retain records of the batches of instruments that have been sent/received from the sterilization service provider.
- The contract should also state that if there is an error in the sterilization process, all the instruments with the same batch number shall be resterilized.

Annex E **(normative)**

Method for packing and sterilizing instruments

Prior to sterilization, dry instruments shall be packed in an appropriate sterilization packaging, e.g. sealed pouch(es) or sterilization boxes.

Packing the instruments:

- Pack each cleaned and dried instrument.
- The components of a tube that can be disassembled may be packed separately.
- Pouch(es) shall be sealed according to the manufacturer's instructions.

The instruments shall be sterilized in accordance with the manufacturer's instructions:

- Load the sterilizer.
- Set the validated sterilization programme.
- Check the temperature and pressure metres on the steam sterilizer.
- Complete the entire sterilization program, including the drying programme.
- Carefully remove the dry, sterilized pouch(es) from the sterilizer. Do not allow the packaging to be damaged.

Store the instruments in a clean cupboard or drawer.

Annex F **(informative)**

Consent Form

F.1 Example of a consent form

An example of a consent form, which can be adopted, is given in [Table F.1](#). It can be adjusted according to national requirements.

Table F.1 — Example of a consent form

Details of tattooist and client	
1. Name of tattooist: Business name and address: If convention state location and contact details:	
2. Name of client: Address and contact details:	
3. Date of birth of client: Proof of age document produced:	
4. Brief description of the tattoo to be carried out and location on the client's body.	
5. Record that medical history and health status of the client has been checked, together with advice provided.	The client should inform the tattooist about their health status and medical history. The client should check the list of conditions in the attachment to assess their suitability for the tattoo.
6. Confirmation that the client was informed of side effects, risks and potential complications.	I have been informed about the risks and possible complications and I understand this information.
7. Confirmation that the client was informed of aftercare requirements.	The aftercare procedure has been clearly explained to me and I understand the actions and precautions I need to take. I have been provided with my own copy of the aftercare procedure in writing.
8. Inks and needles used.	List tattoo inks used by colour, brand name, supplier/manufacturer and batch/lot numbers. This could be completed after the tattooing session. List needles used by configuration, supplier and batch/lot numbers.
9. Declarations.	
Client declaration:	
	<p>"I confirm that the above information and statements provided by me are correct to the best of my knowledge and belief; that I am over the age of consent for this procedure; that I am not currently under the influence of alcohol or non-prescribed and illegal drugs or any substances that may alter my perception, freewill and judgement".</p> <p>"I give my consent to tattooing as described being carried out by the named tattooist."</p> <p>"I have considered the attachment of this consent form."</p> <p>"I confirm that the tattooist can keep a record of this consent form."</p> <p>"I am aware of and accept the risks and possible complications associated with being tattooed."</p>

Table F.1 (continued)

Signature of client:	
Date:	((first tattooing session))
Signature of client:	
Date:	((further tattooing sessions))
Signature of parent/guardian confirming consent (if required according to national legislation):	
Date:	
Tattooist declaration:	
	“I confirm that the tattooing will be carried out under hygienic conditions using the appropriate sterile instruments and safe techniques and in accordance with EN 17169 or according to the national requirements.”
	“No form of anaesthetic will be administered by me for this procedure.”
	“I confirm that the client has been offered a copy of this signed consent form and has been advised to retain the information.”
Signature of tattooist:	
Date:	

In case of doubt, include type of proof of age document produced and document the consent of parent/guardian if required, e.g. according to national legislation.

If more tattoo sessions are planned, the client should review their health status and sign before each session. If there has been a change to their health status, their consent should be reconfirmed on a new consent form.

F.2 Client information to accompany the consent form

Read the following information carefully and inform the tattooist if you have any doubt about your suitability for the tattoo.

Tattooing and the healing process can be associated with risks and possible complications as has been explained to you. You will receive aftercare instructions to help minimize the effects.

Tattooing is normally associated with pain, redness and swelling. If these symptoms worsen during the healing process, this can be a sign of infection and you should consult a physician.

Some complications can be related to your health status. It is important for your safety that the tattooist is informed. Additional preventive measures could be necessary.

Tattoos are permanent and, depending on the inks used, may not be removed effectively.

If in doubt, the procedure should be postponed and medical advice should be obtained.

Do not have a tattoo:

- if you are pregnant or breastfeeding;
- if you are under the influence of alcohol or non-prescribed and illegal drugs;
- on a mole or on a melanoma resection scar.

The following conditions may pose a higher risk of complications:

- 1) Skin:
 - a) skin infection irrespective of the location and the type of the infection;
 - b) allergies (specify if you have any allergy e.g. latex allergy, allergy to metals and preservatives);
 - c) areas of skin that appears damaged or abnormal, including birth marks;
 - d) any skin disease in the active state (e.g. eczema, psoriasis);
 - e) areas that have been subjected to plastic surgery or radiotherapy including recent scars and keloids (according to medical advice);
 - f) an area that was previously tattooed until healing is complete;
 - g) an area that recently had a tattoo removed by laser or by any other method if the wound has not yet healed.
- 2) General conditions:
 - a) haemophilia or other blood clotting disorders;
 - b) epilepsy, cardiac and vascular disorders;
 - c) known allergies [see in [E.2, 1](#)], e.g. latex allergy];
 - d) diabetes;

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- e) autoimmune diseases;
- f) immunosuppression and conditions with compromised immune system;
- g) sarcoidosis.

If you have one of the above, and you still want to get a tattoo, consult first with your physician and ask for advice.

This is a non-exhaustive list of examples which can be adapted and adopted.

Annex G **(informative)**

Aftercare

G.1 General

This is an example of good practice and includes the essential components of aftercare but local variations within this context are also acceptable.

The tattooing procedure causes an injury which disturbs the integrity of the skin and creates an entry portal for microorganisms. A fresh tattoo, completed in hygienic conditions on clean and healthy skin can be considered as an uncomplicated superficial wound. Good aftercare will promote fast wound-healing and reduce the risk of infections.

The tattooist should provide the client with oral and written information concerning tattoo aftercare.

The aftercare advice should contain the following information:

- 1) the need for handwashing before the client touches the tattoo wound;
- 2) descriptions of the aftercare treatments which:
 - i) the tattooist will carry out immediately upon completion of the procedure;
 - ii) the client is recommended to carry out during the healing period;
- 3) activities to avoid during the healing period;
- 4) descriptions of signs of normal healing and signs of infection or allergy and action to be taken if infection or allergy is suspected.

The tattooist should explain to the client the importance of good hygiene.

All aftercare procedures should be performed with clean hands or whilst wearing gloves. In general, touching the tattoo should be minimized and hands should be washed before touching the tattoo.

G.2 Aftercare treatment

G.2.1 Aftercare by the tattooist immediately after the procedure

Wipe the tattooed area with water of drinking water quality or an appropriate wound cleaning solution and dab the surface dry with clean gauze or tissue.

Protect the tattoo. Four different options (a, b, c, d) are given below.

Tattoos on the face and the scalp (e.g. permanent makeup, micro blading) can also be treated as specified in the paragraphs below but would not be covered with a dressing.

a. Hypoallergenic aftercare ointment

Apply a hypoallergenic aftercare ointment, (collected from the original container with a single use device or transferred from the original container with a single use device).

Cover with either a non-adhesive dressing secured with hypoallergenic tape or with self-adhesive plastic film (food-wrap); this should be clean, taken straight from the pack and used immediately.

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The client can remove the dressing or plastic film after a few hours or the next day, depending on the advice of the tattooist.

b. Clean gauze pad

Cover with a clean gauze pad:

This is a temporary measure to protect the wound while the client is travelling home. The client can remove the gauze pad after (2 to 4) h and start aftercare treatment at home, see [G.2.2](#).

If the gauze pad is allowed to adhere to the fresh wound and dry, removal will be painful and will delay healing. Removal can be facilitated by moistening the adhering gauze pad with clean water.

c. "Second skin like" bandage

Cover the tattoo with a "second skin like" bandage, such as foam dressing, colloidal bandage or with a transparent polyurethane foil adhesive dressing. The foil or bandage can remain on the wound for (4 to 6) days as long as it feels comfortable and does not leak wound fluid. The wound will then heal without forming a scab.

d. Spray plaster

Cover with a spray plaster:

The spray will dry out within a couple of minutes, after which the client can wear clothing over the tattoo. The spray plaster will provide protection for (3 to 5) days.

G.2.2 Aftercare at home

G.2.2.1 General

Wash your hands before wound care.

G.2.2.2 a. and b. group

- 1) Remove the non-adhesive dressing, the plastic film or the gauze pad.
- 2) Gently wash the tattoo with clean hands only, cold or lukewarm water and a hypoallergenic mild soap.
- 3) Rinse soap off thoroughly. Dab tattoo dry with a fresh clean towel or paper towel, alternatively allow the tattoo to air dry. Do not wipe or rub dry.
- 4) Apply a light film of hypoallergenic aftercare ointment.
- 5) Re-cover the tattoo with a new non-adhesive dressing or plastic film.
- 6) Repeat steps 1) to 5) two or three times daily for (2 or 3) days. A soft pliable scab will start to cover the tattoo.
- 7) After 3 days continue to keep the tattoo moist by using an aftercare hypoallergenic ointment until any scab has gone. Do not re-cover the tattoo.
- 8) When the scab is completely gone you should use an unperfumed moisturising lotion several times a day to stop the tattoo from drying for (2 to 3) weeks.

G.2.2.3 c. and d. group

- 1) Leave the second skin bandage, foil or spray plaster on the tattoo for (4 to 7) days.
- 2) Remove it gently when it starts to peel off.
- 3) Gently wash the tattoo using clean hands only, cold or lukewarm water and a hypoallergenic mild soap.

- 4) Rinse soap off thoroughly. Pat tattoo dry with a fresh clean towel or paper towel, alternately allow the tattoo to air dry. Do not wipe or rub dry.
- 5) Keep the tattoo moist by using an aftercare hypoallergenic ointment. Do not re-cover tattoo.
- 6) When the wound is completely healed, an unperfumed moisturising lotion should be used several times a day to stop the tattoo from drying for (2 to 3) weeks.

G.3 Activities to avoid during the healing period

- Avoid taking a bath, swimming and using a sauna until the tattoo is completely healed. Showering is acceptable according to the advice of the tattooist.
- Avoid sun-exposure and artificial tanning (sunbeds) for at least 2 months to reduce the risk of abnormal pigmentation. If sun-exposure cannot be avoided high protection factor sunscreens can be used only on a completely healed tattoo but their protection is limited. Incompletely healed tattoos should not be exposed to direct sunlight and if this is unavoidable, they should be covered. Sunscreens should be used only on completely healed tattoos.
- Wear clean clothing in contact with a fresh tattoo and during the healing period.
- Do not pick crusts or loose skin during the healing period and avoid scratching.
- Skin disinfectants (antiseptic) can interfere with the healing process. Antibiotics can lead to bacterial antibiotic resistance and allergy. Neither should be used without medical advice.

G.4 Descriptions of signs of normal healing and signs of infection and allergy

G.4.1 General

The client should be informed about normal versus abnormal signs of wound healing.

G.4.2 Normal signs

- Weeping (clear or pink fluid mixed with tattoo ink) is a normal occurrence in the first days. When weeping is excessive, the bandage will get saturated and start to leak. In this situation changing the dressing more frequently is advised.
- Redness in the tattooed area.
- Mild swelling is normal in the first hours to days but should decrease every day.
- Fever or chills can occur within the first 12 h after tattooing, if persistent or severe it should be considered as a sign of infection and immediate medical assistance is required.

G.4.3 Abnormal signs

G.4.3.1 Signs of infection

- increasing weeping;
- discharge of yellowish to green sticky fluid;
- an unpleasant smell;
- increasing painful redness, spreading around the tattooed area;
- increasing throbbing and burning in and around the tattooed area;
- immobility of, or difficulty in moving, a limb/digit/part of the body;

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- red lines spreading over the skin; e.g. red lines tracking from a recent tattoo on the wrist or hand continuing over the forearm towards the upper arm. This can be associated with sepsis (blood poisoning). Immediate medical attention should be sought if this is observed;
- high fever or persistent fever and flu-like symptoms are signs of serious infections. Immediate medical attention should be sought if this is observed.

What to do in the case of an infection?

Consult your physician or local health professional. The tattooist should be notified as well.

People in a high risk category:

People with some conditions (e.g. diabetes, immunosuppression etc.) have a higher risk of developing a wound infection. They should seek immediate medical attention if signs of infection occur.

G.4.3.2 Signs of allergy

Clients, especially clients with a pre-existing contact allergy for certain substances (e.g. nickel, preservatives, antiseptics and lanoline), can experience an allergic reaction in the tattooed and surrounding areas, sometimes spreading over the body. An allergic reaction can occur within hours, weeks, months or years after the tattooing process and can present as a rash with redness and itching, sometimes small blisters and the exudate is clear.

What to do in the case of an allergic reaction in the first days after the procedure?

In the case of an allergic reaction in the first days, encourage the client to stop the use of all products and consult a physician. This is difficult to treat and needs specialist advice.

Where the client informs the tattooist of a concern or problem, the tattooist is advised to keep records of any action taken and advice given.

Annex H **(normative)**

Hand hygiene

How to carry out hand hygiene

- a) Where indicated, hand washing shall be performed using soap and water. Hand disinfection shall be performed before tattooing (e.g. according to national regulations where they exist).
- b) Hygienic hand rubs shall only be used when hands are visibly clean.

[Figure H.1](#) provides an example for hygienic hand washing and disinfection.

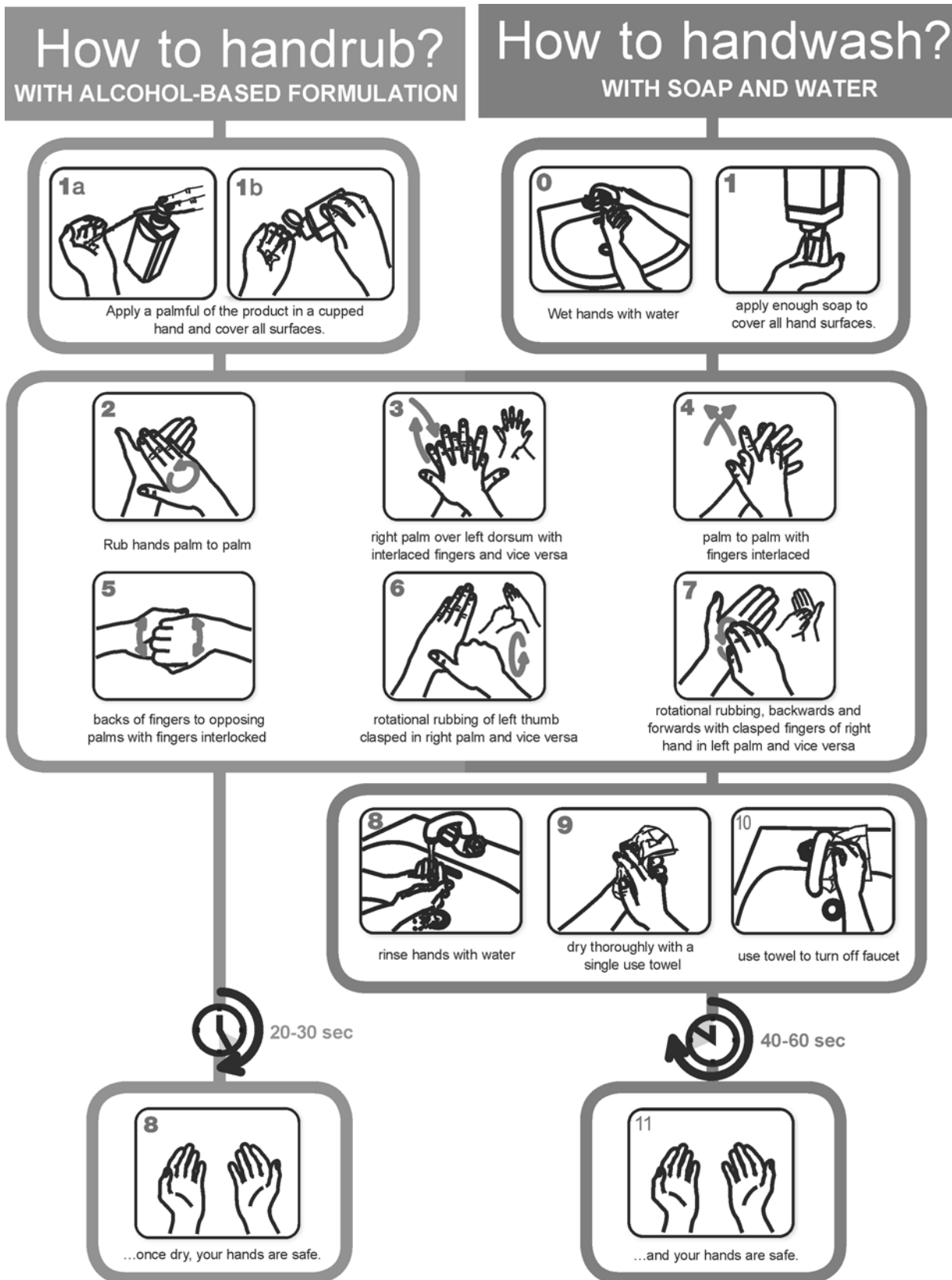


Figure H.1 — Diagram of handrub and handwash

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