Health and Safety Executive
HSE

# Health & Safety Executive/Local Authorities Enforcement Liaison Committee (HELA)

## Local Authority Circular

- **Subject:** Cosmetic Treatment
- **LAC Number:** 14/1
- **Open Government Status:** Fully Open
- **Keywords:** Micropigmentation, semi-permanent tattooing, semi-permanent make-up
- **Version:**1
- **Issue date:** 21.8.2006
- **Review date:** 21.8.2011
- **Author Unit/Section:** Commercial & Consumer Services, Transport & Utilities (CACTUS)

**To:** Health and Safety Enforcing Authorities

**For the attention of:** Local Authority Health and Safety Enforcement Managers, Health and Safety Regulators and others

**This Local Authority Circular (LAC) provides technical guidance to enforcement officers and others on health and safety issues associated with micropigmentation.**

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## Micro-pigmentation, semi-permanent tattooing and semi-permanent make-up

## Contents

## Purpose and scope of this Local Authority Circular

1 This Local Authority Circular (LAC) provides technical guidance to enforcement officers and others on health and safety issues associated with micropigmentation.

2 Although the document is primarily intended for health and safety enforcement officers, it may also be circulated and made available to those involved with micropigmentation and similar treatments (manufacturers, importers, suppliers, purchasers, users of the equipment and the person undergoing micropigmentation) to ensure: -

- That health and safety risks to those involved are adequately controlled; and
- Consistent standards are applied and achieved.

3 This guidance does not cover other skin piercing activities such as cosmetic (body) piercing - this is covered in Local Authority Circular (LAC) 76/2.

4 Health & Safety Executive (HSE) funded laboratory research, information gathering and industry contact related to micropigmentation, tattoo removal and pigment quality have contributed to the revisions within this document.

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## Key messages

- Effective infection control is essential.

  The design of some micropigmentation equipment allows pigments and body fluids to track back into parts that cannot be effectively cleaned, disinfected or sterilized. Prohibition notices have been served in the past to prevent further supply of such equipment. Prohibition action is very likely to be necessary where they are found
- to be still in use.

  Enforcement action on issues associated with,

  - The use of equipment falls to local authorities (LAs)

    Peripatetic use (mobile operators/those without fixed premises)/design/manufacturing/supply falls to the
  - HSE
- Examples of known equipment and photographs can be found in Appendix twelve.

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## Definitions and legislation

**What is micropigmentation?**

5 Micropigmentation is the insertion of pigment into the dermal layer of the skin. It is used for:

- Semi-permanent / permanent make-up, such as lip and eye liner
- Body art/tattoos; and
- Medical application such as camouflaging scar tissue, redefining cleft lip, areola (after breast surgery),

- pigmentation of eyebrows for alopecia sufferers and vitiligo for people who have skin pigment loss.

The micropigment differs from traditional tattoo inks in that typically, it consists of fine particles in a liquid suspension, as opposed to the fully dissolved inks used for traditional tattooing. The particulate nature of micropigments, and the various 'natural pigments' reputedly used in their manufacture, are said to contribute to their semi-permanency. This may be due to a greater susceptibility of particulates to the activity of the body's immune system, which ultimately fades the colouration. Various operators offering micropigmentation-based treatments claim that skin colouration will last anything from 1 to 5 yrs, depending on skin type and level of exposure to the sun. In some cases a less specific period of 'several years' longevity is described. Peer-reviewed reports of nipple-areola tattooing done with iron oxide and titanium dioxide pigments describes post-treatment checks at up to75 months; all tattoos remained at this stage, though ten percent of tattoos needed a touch-up to correct for excessive fading. Nearly 60% of tattoos were ultimately lighter than the normal (Spear & Arias, 1995).

## Summary of relevant legislation

6 The Government has recently amended the Local Government (Miscellaneous Provisions) Act 1982 by means of the Local Government Act, 2003 (Section 120), to give LAs new specific powers to regulate businesses providing semi-permanent skin-colouring (e.g. micropigmentation, semi-permanent make-up and temporary tattooing) and cosmetic piercing (body piercing and ear piercing). This change in the law came into force on the 1 April 2004. This extends the powers that local authorities already had in relation to tattooing, ear piercing, electrolysis and acupuncture. The Department of Health has published guidance about the change in the law: *Local Government Act 2003: Regulation of cosmetic piercing and skin-colouring businesses – guidance on section `120 and Schedule 6*. The document can be down loaded from The Department of Health website [1]

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7 The London local authorities mainly use the London Local Authorities Act 1991, which includes powers to regulate micropigmentation businesses.

8 There is a legal requirement for businesses involved in *permanent* tattooing to register under the Local Government (Miscellaneous Provisions) act. Previously, some local authorities have added a memorandum of understanding to byelaws under this Act, which defines tattooing to include micropigmentation. However, some LAs have considered micropigmentation to be outside the definition of tattooing, in that it is not 'permanent marking,' and have not registered the business, leading to inconsistency. See Appendix One for further information relating to this issue.

9 The Health and Safety at Work etc. Act (HSWA) 1974 applies to all employers, whether a business is registered with its LA or not; it serves to protect employees and others, such as members of the public, who may be affected by a work activity.

10 Local authorities will enforce the provisions of the HSWA 1974 where micropigmentation takes place in premises to which the Health and Safety (Enforcing Authority) Regulations 1998 Regulation 3 Schedule 1 applies. I.e. beauty salons, leisure centres, high street operators, exhibitions etc.

11 HSE is the enforcing authority where such work is carried out peripatetically. i.e. where someone works at a variety of locations and has no fixed premises.

12 Additionally, HSE also enforces the Supply of Machinery (Safety) Regulations, 1992 [as amended 2005, and by the Supply of Machinery (Safety) (Amendment) Regulations 1994], (SMSR) governing the supply of micropigmentation machinery.

13 **Any potential breaches of these regulations noted during inspections should be passed to HSE via the Enforcement Liaison Officer (ELO)**. See Appendix One for further information on the supply of equipment.

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## Background

14 In 2002-03 an initial investigation was carried out by HSE following a complaint received by Tunbridge Wells Borough Council. The complaint related to the supply of semi-permanent tattooing equipment in that area. The recipient of the equipment believed that it could not be effectively sterilized between clients as a result of its design features. This first case led to a wider investigation of equipment and suppliers, and to the preparation of the LAC 14-1 guidance document by HSE.

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## Appendix 1: relevant legislation

### Tattooing of Minors Act 1969

15 The tattooing of Minors Act 1969 pre-dates the widespread use of micropigmentation in the UK. It defines a tattoo as "…the insertion into the skin of any colouring material designed to leave a permanent mark", and prohibits tattooing (as per the definition) of anyone in the Great Britain under the age of 18 years. Some companies advertise micropigmentation as semi-permanent, though others state that it is permanent, so the applicability of this Act is dependent on the nature of the advertised procedure.

16 Standard tattoos are a well-known form of body adornment but are also a form of body modification because they are permanent skin alteration unless removed. Laser treatments have been available for some years for ink tattoo removal, and this method is related to laser use for the removal of skin blemishes. However, chemical tattoo removal treatments are now being widely promoted and involve the injection of various chemicals in to the dermal layer, usually using a procedure that closely resembles that used for pigment insertion (see also Appendix 9). Removal treatments may result in incomplete removal and or even scarring of the affected area, and their use should therefore be given careful consideration. In view of the above, and following any first consultation related to facial tattooing of any kind, a period of reflection is recommended due to the potential impact that such treatments may have on the client.

### The Local Government (Miscellaneous Provisions) Act 1982

17 If an LA has adopted the Local Government (Miscellaneous Provisions) Act 1982[1], this allows it to make byelaws on acupuncture, semi-permanent skin-colouring and cosmetic piercing. The person(s) carrying on the business and the premises are required to register with the LA that enforces the provisions of the byelaws. These cover the cleanliness of the premises, fittings, equipment and persons carrying on the business. These businesses are inspected to ensure that they comply with the byelaws.

[1] As amended by The Local Government Act 2003 Section 120.

18 The Local Government Act 2003 amended the Local Government (Miscellaneous Provisions) Act 1982 so as to include a definition of semi-permanent skin colouring: 'the insertion of semi-permanent colouring in to a person's skin'; this approach allows for similar activities to be covered in the future. This clearly covers a wide range of such activities. The legislation does not, however, apply to semi-permanent skin-colouring (or tattooing, cosmetic piercing and electrolysis) carried out by or under the supervision of a medical practitioner (e.g. registered with the General Medical Council), or to the premises on which such activities take place.

### Greater London Council (General Powers) Act 1981

19 The 1981 Act is legislation that states - that no person may carry out acupuncture, tattooing or cosmetic piercing in their area unless he and any business premises are registered. If such activities are carried out by a registered medical practitioner, there is no requirement to register. The Borough Council may make byelaws for the purpose of securing the

cleanliness of premises, instruments, equipment and persons. Books, cards or forms must also be kept by persons registered under this section, recording their activities in connection with the practice of business in respect of which they are so registered and that appropriate entries are made in such books, cards or forms. It is believed that only a small number of London Borough Councils use this legislation, which has now been repealed, except in relation to un-expired licences or registrations under the Act.

### London Local Authorities Act 1991

20 This is legislation that states - No person shall carry on an establishment for special treatments without first obtaining a licence from a participating council. Any person working in an establishment licensed for the provision of special treatments must themselves be registered with the Council for the provision of those treatments.

21 An 'establishment for special treatment' is defined in the Act as any premises used or represented as being, or intended to be used for the reception or treatment of persons requiring massage, manicure, acupuncture, tattooing, cosmetic piercing, chiropody, light, electric or other special treatments of a like kind or vapour, sauna or other baths.

22 Micropigmentation has been included within these definitions and most London Authorities license special treatments.

23 Conditions can be attached to licences that may cover items such as safety of equipment, hygiene practices, specified age limits, hours of operation etc.

24 Premises are exempt from the need to license if they are not used for gain or reward, or where the special treatment is carried out by or under the supervision of a medical practitioner registered with the General Medical Council or persons who are bona fide members of a body of health practitioners.

25 Health practitioner is defined as 'a person who uses his skills with a view to the curing or alleviating of bodily diseases or ailments, but does not include a person whose skills are employed mainly for cosmetic alteration or decorative purposes'.

26 A list of bodies of health practitioners currently granted exemption is provided to all London authorities that have adopted the Act.

### Health and Safety at Work etc Act (HSWA), 1974

27 Ultimately, whether LAs register the business or not, the HSWA, 1974 applies to all employers, employees and self-employed people. It also protects people not at work such as members of the public, who may be affected by a work activity. As with any business, Sections 2 and 3 of the HSWA, 1974 can be applied at any micropigmentation premises to ensure the suitability of the premises, safety of staff employed and to ensure a safe treatment environment for the public affected by the business. Specifically:

- **Section 2** of the Act places a duty upon every employer to ensure the health, safety and welfare of their employees, so far as reasonably practicable.
- **Section 3(1)** of the Act is particularly applicable to business premises where the public may be affected by business activity, and states that: 'It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, *so far as is reasonably practicable,* that persons not in his employment who may be affected are not exposed to risk to their health or safety.'
- **Section 3(2)** of the Act places a similar duty on every self-employed person.

### HSWA etc. (1974) and training

28 The HSWA etc., (1974) also requires employers to provide whatever information, instruction, training and supervision that is necessary to ensure, so far as is reasonably practicable, the health and safety of their employees. An employer is therefore required to provide adequate employee training to ensure that they can carry out their work safely, and this may include basic first aid training and infection control guidance, the latter available within this document. At this time there

remains no nationally approved UK training course for micropigmentation, although a number of commercially run courses are available, usually via equipment operator / suppliers. Habia, the Standards Setting Body for the hair & beauty sector, has set National Occupational Standards (NOS) for micropigmentation by working with industry practitioners. These are available for download from www.ukstandards.org.uk [2] or from Habia at www.habia.org [3]. Efforts to develop National Occupational Standards for tattooing and piercing failed to obtain industry agreement. Despite this, the process of trying to develop NOS with operators did stimulate the formation of the Tattooing and Piercing Industry (TPI) Union, which is a branch of the GMB Union. TPI has a UK wide membership with branches in Wales, N Ireland and Scotland, and has indicated its desire to raise standards within the industry. A Code of Practice for tattooing and piercing activity is available from the TPI Web site at: www.tpi.org.uk [4]. In addition, the Qualifications and Curriculum Authority does provide a Further Education course in Beauty Therapy, and this is said *To provide students with a broad educational base for a career in a rapidly changing service industry – beauty;* The course contains microbiology, anatomy and physiology components.

### Management of Health and Safety at Work Regulations 1999

31 These regulations require employers and the self-employed to assess the risks to employees and non-employees such as members of the public, arising from the conduct of their undertakings. Employers with five or more employees need to record the significant findings of any risk assessment. Appropriate training considerations, as described above, are an important component of minimising risk within any working environment.

### The Workplace (Health, Safety and Welfare) Regulations 1992

29. These regulations contain important duties on the maintenance of equipment in workplaces, which would apply to units where micropigmentation services were offered. They also cover issues such as ventilation, room temperature, lighting, cleanliness, room dimensions, workstations, flooring, windows, doors, sanitation and rest facilities. These duties are owed to employees.

### The Provision and Use of Work Equipment Regulations 1998 (PUWER)

30. These regulations focus on work equipment rather than the workplace and apply not just to employers but also to anyone having control of work equipment or supervising its use. PUWER has clear application to equipment used for micropigmentation, which by definition is not only work equipment but carries specific risks both to users and clients. Duties relate to the need to ensure that equipment is fit for purpose, is used under suitable conditions, is maintained and inspected; that use is restricted where it is likely to involve specific health and safety risks, that information and training are provided to users; and that protective arrangements are put in place in regard to dangerous parts. There are also duties in relation to specified hazards, equipment used at high or low temperatures, stop controls and mobile work equipment.

### The Supply of Machinery (Safety) (Amended) Regulations 1992 [as amended 2005, and by the Supply of Machinery (Safety) (Amendment) Regulations 1994] (SMSR)

32 These regulations place duties upon those who supply machinery including manufacturers, importers and others in the supply chain. They set out the essential requirements, which must be met before machinery may be supplied in the UK and the rest of the EU. If at least one of the machine parts moves, and if the movement results from external energy e.g. electricity/battery, then the machine falls into the remit of these regulations. By this definition, almost all micropigmentation equipment is classed as machinery. The exceptions are manually operated needle pens with no moving parts. There are 3 main parts to the requirements:

- The responsible person (Manufacturer if in the EEA; EU plus Norway, Iceland and Liechtenstein, or if outside then either the importer or the manufacturers official representative based in the above), should ensure that machinery and safety components satisfy the relevant **essential health and safety requirements (EHSRs)**.

- Schedule 3 of the regulations details the essential health and safety requirements and the machinery must be accompanied by **instructions for safe use and maintenance**.
- The responsible person must issue a **declaration of conformity**, which is issued with the finished product so that it is available to the user. The exception is if the manufacture outside the EEA takes on the duty to CE mark and issue a declaration of conformity. In this case the importer only need check that these are provided and that the equipment is safe. This declaration will contain various details such as the manufacturer's address, the machinery type and serial number, the European Supply Directives it complies with and, if built to a harmonised European standard, its reference number.
- The responsible person should affix the **CE marking** if they are satisfied it is safe and it meets the EHSRs.

33 The HSE is responsible for enforcing these Regulations in relation to machinery supplied for use at work; any failures to comply with these regulations should be passed onto the HSE in the usual way.

### Control of Substances Hazardous to Health 2002 (COSHH)

34 These regulations require employers and self-employed to prevent, or where is not reasonably practicable, control the exposure of employees and others such as members of the public to hazardous substances. This includes exposure to chemicals and biological agents. COSHH sets out basic measures that employers must take to:

- Assess the risks associated with hazardous substances, e.g. liquids, aerosols, volatile fumes;
- Implement any measures needed to prevent or control exposure; and
- Establish good working practices.

In particular, assessments will almost certainly need to be made of:

- The use and correct storage of the cleaning products and disinfectants required to effectively clean micropigmentation equipment; and
- Contact with body fluids.

35 COSHH also requires that sufficient information, instruction and training be provided to employees. This should include

- The names of substances they work with;
- The main findings of the risk assessment, including handling of materials which may be contaminated with blood products;
- The precautions they should take to protect themselves and other employees, including disposal of materials containing blood products;
- How to use personal protective equipment and clothing; and
- Emergency procedures to be followed, e.g. first aid, spillages.

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## Appendix 2: pre-consultation with the client

36 A consultation should occur with the client before any treatment is carried out. Records should be kept of this consultation, and a 'cooling off' period should be recommended for those treatments that are particularly visible, e.g. facial treatments. Many traditional tattooists photographically record their work for use as in-house advertisements or for reference if further 'touching up' of artwork is required. However, if this were done it would require customer agreement, anonymity at the customer's request and a guarantee of security for image storage. The following items should always be discussed:

### Medical history to include any:

- Eczema
- Psoriasis and other chronic skin conditions excluding acne and disorders of pigmentation
- Haemophilia and other bleeding disorders
- Heart disorders
- High/low blood pressure
- Medication
- Nursing mothers
- Pregnancy
- Epilepsy
- Diabetes
- Autoimmune disease or other conditions or medication causing immuno-suppression (e.g. cancer treatments)
- Allergies* - especially nickel allergy
- Any other contra-indications

**Note:** Micropigmentation of clients with any of the above conditions is not necessarily contraindicated: such customers should consult their doctor for a certificate stating that whether or not micropigmentation is contraindicated.

*It may be appropriate to patch test skin products if any existing sensitivities are indicated

### Other factors/items to be taken into consideration include:

- Natural skin tones
- Pigment colour selection
- Choice of area(s) to be treated
- Photographic record of the area treated

### The treatment plan should include:

- After care advice (written and verbal)
- Associated hazards and risks**, e.g. is the client suffering from any infections that may pose a risk to themselves or the operator as a result of the treatment?

**Such information may be unreliable and standard precautions should be in place to protect both parties, regardless of the response. However, if a client is suffering from a serious and incurable infection, such as a blood borne-virus infection, it may be inappropriate for them to have treatment undertaken.

37 If there is a history of relevant medical conditions, the client should be advised to consult their GP for advice on their suitability for micropigmentation. A signed certificate should be obtained from the GP if this step is deemed necessary.

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## Appendix 3: infection control

38 It is essential when carrying out micropigmentation that infection control considerations are paramount. As with all skin piercing activities there is a risk of blood borne virus transmission, such as hepatitis B, hepatitis C and HIV, if hygienic procedures are not followed. Bacterial infection of treated sites – or even septicaemia (blood poisoning) - may also arise if

infection control is poorly maintained. The Department of Health has produced model byelaws for local authorities to use under the Local Government (Miscellaneous Provisions) Act 1982 which relate to the hygiene and cleanliness of premises, the person carrying out micropigmentation and the equipment used. This circular should be read in conjunction with these model byelaws [5]

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### Person carrying out micropigmentation

39 It is recommended that the person carrying out micropigmentation be immunised against hepatitis B to protect both themselves and the client. Because of the occupational nature of the requirement, an operator may be charged by his / her GP for this course of injections. Immunisation should not be regarded as a replacement for good hygiene standards. There is still no vaccine available against HIV or hepatitis C, so any potential contact with blood and other body fluids should be approached with all necessary precautions. Anyone handling sharps is also advised to be up to date with their tetanus immunisation. Immunisation can be arranged through a general practitioner and advice on these issues is given in, Immunisation Against Infectious Disease (The Green Book) [6]

. This information has recently been updated and is accessible on Department of Health website.

### Work surfaces

40 All work surfaces, couches, seats etc should be designed so that they are smooth, impervious and can be effectively disinfected by wiping with a suitable disinfectant between clients to reduce the risk of cross infection. Any products used should be chosen with care to avoid causing chemical damage to such work surfaces.

### Personal hygiene

41 A good standard of operator personal hygiene is essential in controlling the risk of infection. Cuts or grazes should be covered prior to starting treatment. The operator's nails should be clean and short and eating and drinking should be prohibited in the clean treatment area.

42 **Hand-washing** is an important procedure for preventing the spread of infection. Hand washing is best performed using liquid soap and running water in a purpose-designed basin, and with effective drainage. Water should be supplied hot and cold via a mixer tap, preferably via a foot, elbow or lever operated tap system, and hands must be dried using good quality disposable paper towels. The use of nailbrushes is not advocated, as they are a source of microbial contamination. It is good practice to have hand-washing posters displayed that are routinely rotated/changed. Hand-washing is particularly important:

- Before and after carrying out micropigmentation
- Whenever hands become accidentally contaminated with blood, body fluids or secretions;
- After removing protective gloves (see below);
- After visiting the toilet;
- Before handling food and drinks;
- After smoking. Smoking should not be allowed during micropigmentation due to the risk of transferring bacteria from the operator's mouth - via fingers - to the client.

43 Alcoholic hand rub (cleanser) should not be used as a substitute for effective hand- washing and should only be used on hands that are already physically clean. When decontaminating hands using an alcohol hand rub, hands should already be free from dirt and organic material. The hand rub solution (70% alcohol and an emollient) must come into contact with all surfaces of the hand. The hands must be rubbed together vigorously, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers, until the solution has evaporated and the hands are dry. After 3 uses, hands will begin to feel sticky and will need to be washed using soap and water. Alcohol gel must never be

used as when hands are in need of washing with soap and water (see above)

### Personal Protective Equipment (PPE) and appropriate clothing

44 In order to protect the operator from body fluids and protect the client from infection it is essential that gloves and the following PPE be worn:

### Gloves

45 Examination style gloves should be worn during the treatment to protect the operator during contact with bodily fluids and tissues. This barrier also protects the client from any microorganisms harboured on the operator's hands, but should **NOT** be regarded by an operator as a substitute for good hand washing. Hands should first be washed and thoroughly dried prior to putting on gloves, and:

- Disposable examination-style gloves should be worn during micropigmentation procedures and must be disposed of between clients. Fresh gloves must be used at commencement of every new procedure. Latex allergies are becoming common with prolonged use of latex gloves, and the use of vinyl and nitryl-based glove materials will avoid sensitisation. (see also Relevant Publications section);
- If latex gloves are worn, those with low protein content should be chosen. Polythene or powdered gloves must never be used;
- Gloves made from acceptable alternatives to latex must be appropriately CE marked for use with biological agents up to Hazard Group 2, and must meet the appropriate British Standard;
- Gloves should always be changed if punctured at any time during a procedure or when otherwise contaminated during procedures, e.g. if there is any possibility of contamination from the previous client;
- Hands should always be washed after glove removal;
- Used, single-use gloves should be disposed of to clinical waste receptacles and should never be re-used, or washed for re-use; and
- Domestic style gloves should only be used for equipment cleaning;

### Clothing

46 Clean, washable clothes are suitable for use by the operator and ideally, a single-use plastic apron should be worn and should be disposed of between clients in to a clinical waste receptacle.

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## Appendix 4: cleaning and disinfection

### Important note

47 Any re-usable equipment used during micropigmentation will require disinfection or sterilization before re-use, and it is essential that thorough cleaning and drying of any re-usable equipment is undertaken prior to either of these treatments. Recommended facilities for any washroom include a deep sink for any manual cleaning plus hand washbasin. The cleaning area should ideally provide space enough for demarcation of clean & dirty areas.

### Definitions:

**48 Cleaning** - a process that physically removes contamination, including some microorganisms, but does not necessarily destroy a significant proportion of the microorganisms originally present. The reduction of microbial contamination cannot be defined and will depend on many factors including the efficiency of the cleaning process and the initial level of organic residue (soiling) present. Cleaning of equipment and work surfaces is best achieved using detergents compatible with the materials from which the equipment and work surfaces are made.

**49 Disinfection** - reduces the number of viable microorganisms but it may not necessarily inactivate all bacteria, fungi, viruses and spores. Disinfection does not achieve the same reduction in microbial contamination levels as sterilization and it lacks the treatment quality assurance of steam sterilization. The efficacy of the disinfection process will be reduced if prior cleaning has not been performed.

**50 Sterilization** - renders an object free from viable microorganisms, including bacterial and fungal spores that may survive disinfection treatments. Use of UV light / glass bead sterilizers are not considered suitable for adequate sterilization and should not be used.

**51 Ultrasonication** - Ultrasonication is an efficient cleaning method and operates using a process known as cavitation. This cleaning effect attacks every surface, including apertures, lumens and recesses. Cleaning agents are added to the bath and these are usually supplied with the equipment, or else need to be recommended for use by the equipment supplier. A cleaning effect occurs wherever equipment is in contact with the liquid; therefore it is an effective way of cleaning the smallest crevices in objects. **NB**. Ultrasonic cleaning is not a disinfection process and items cleaned by ultrasonication must be subjected to a subsequent disinfection or sterilization process as appropriate. Therefore items removed from the ultrasonication bath should be handled with care.

## Cleaning of Equipment - general principles:

**52 Contamination** of micropigmentation equipment may occur either with blood-contaminated pigment tracking back up into the equipment and/or by fine droplet contamination inside or outside the equipment or by contact with contaminated gloves / hands. Parts of the equipment that have become contaminated in either of these ways must either be disposable or able to be cleaned and disinfected, as described in Appendix six.

53 It is strongly recommended that **any re-usable component parts** of equipment, e.g. metal hand piece mid sections, should be made either single use or should be capable of being appropriately steam sterilized (see below).

## Single use equipment

54 Equipment designed as single use must never be re-used and should be disposed of appropriately. (See Appendix seven regarding waste disposal). Items intended for single use should all be clearly marked as such – information on the signage and related issues is available from the MHRA website at: http://www.mhra.gov.uk/ [7]

. Needles and needle covers/tips used for micropigmentation are in direct contact with the client's punctured skin, are designed for single use and must be disposed of after each client. 'More information about single use only parts. The pigments should be dispensed into single use containers, i.e. that are used for only one client, and ideally these should be pre-packed and sterile. Although micropigmentation instruments are not currently regarded as medical devices, relevant information is available from the Medicines & Healthcare products Regulatory Agency (MHRA)-MDA document DB2000 (04), Single-use Medical Devices: Implications and Consequence of Re-use. Some micropigmentation instrument designs consist of a single use, retracting needle sealed within a disposable cassette to isolate any back tracking of pigment. Where present, this design is likely to simplify contaminated sharps disposal.

**55 Heavy contamination** of instruments during individual micropigmentation procedures is unlikely. However, any such contamination, such as blood and other visible soiling should be carefully rinsed off instruments prior to their immersion in the ultrasonic tank, avoiding splashing of the operator.

**56 Ultrasonic cleaners** should be operated in accordance with manufacturers instructions and used with the lid / cover in place to prevent aerosol formation. Instruments should be placed in the basket supplied with the machine; this should be an appropriate size for the device being cleaned. The efficiency of ultrasonic cleaning is improved by the use of a low foaming surfactant or detergent, and this will also avoid the inconvenience of excessive foaming. The choice of detergent and control of the in-use concentration of detergent have a significant effect on cleaning performance, and advice should be sought from both the instrument and detergent manufacturers.

57 The tank of the ultrasonic cleaner should be cleaned with a suitable detergent and soft brush at least weekly, ensuring that the detergent is compatible with the surfaces to be cleaned. The tank should be emptied and refilled with clean solution when the solution has become visibly soiled, or every four hours, whichever is the sooner. As a minimum requirement, the tank should be cleaned at the end of each day and kept dry overnight. De-gassing is necessary after each fill, before instruments are processed.

58 Periodic functional testing of ultrasonic cleaners should be performed - a description of a method can be found in NHS Estates document HTM2030 Washer-disinfectors, Validation and Verification.

### Steam sterilization

59 Steam sterilization is the preferred method of sterilizing equipment as it is rapid, automated, easy to use, reliable, non-toxic and effective when used correctly. A standard bench-top steam sterilizer, (type B of BS EN 13060), will sterilize items that are not hollow, not tubular, not porous (such as fabrics) and not wrapped. If the use of such unpackaged items is not immediate, they must be stored dry, in a clean, disinfected, airtight container. It is good practice to use such items within 3 hours of sterilization or else re-sterilize. Although they have been cleaned and sterilized, these items cannot be regarded as sterile at point of use because they are not being used in a controlled clinical environment, such as an operating theatre. It is therefore likely that the microbiological condition of appropriately stored items will, at worst, be comparable with that of the environment in which they are used.

60 Items that are packaged, hollow or tubular should be sterilized in a sterilizer that has forced air removal (e.g. pre-sterilization vacuum stage) and which has been validated for the intended items. There are two types of porous load transportable steam sterilizer under EN 13060; type S and type B (type N is non-vacuum). Type B is general purpose and, within the manufacturer's limits, should be able to sterilize all that is placed in it. Type S is for specified loads and it is this type that would need manufacturer's approval. For packaged items, the sterilizer must have an effective post-sterilization drying stage. Wet (or damp) packages cannot be regarded as sterile because microorganisms can penetrate wet packaging. Vacuum steam sterilizers are expensive to purchase, run and maintain and are relatively complex pieces of equipment. Their performance in air removal varies considerably. The suitability of a particular sterilizer for a particular load needs to be verified to ensure sterilization. [Further guidance is available in MHRA-MDA DB 2002 (06)].

61 The MHRA now incorporates MDA and MCA and has issued guidance on reprocessing instruments and decontamination of other equipment. The guidance relates to the choice of decontamination method to the infection risk associated with the intended use of the equipment. High risk is associated with items that are in "close contact with a break in the skin" and for these, sterilization is essential. **The MHRA-MDA recommends steam sterilization at the highest temperature compatible with the equipment being processed.**

62 Steam Sterilizers of all kinds are pressure vessels, and as such are subject to regular safety checks under The Pressure Systems Safety Regulations 2000 [8] (PSSR). If using a steam sterilizer, consideration must also be given to the regular checks required to show correct and effective functioning of the equipment. Written documentary records of these checks must kept on the premises for health and safety officers to view. This record keeping is made easier with autoclaves that have printers. The least expensive, non-vacuum autoclaves often have no digital displays / printers, and this makes record keeping more difficult. If the operator has a maintenance / replacement contracts in place this can assist in continuity of use of their steam autoclave, especially if equipment fails. To summarise, MHRA recommends that, in the event of a local inspection being undertaken, the manager of the premises must be able to present both a 'sterilizer process log' (detailing a brief note of every sterilization cycle number) and a 'plant history file' (detailing PSSR inspections, general maintenance, validation and the periodic thermometric test certificates).

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## Appendix 5: equipment used for micropigmentation

63 Micropigmentation is carried out using either non-motorised or motorised devices. Recent investigations have looked only at motorised equipment, which fall under The Supply of Machinery (Safety) Regulations, 1992 [as amended] (SMSR). Non-motorised equipment is pen like, with either single or multiple needles. Needles should always be regarded as one use only, and handles should only be re-used if the manufacturer has designed them to detach from the needle for cleaning and steam-sterilization.

64 Motorised equipment ranges from the simple hand-held device connected to a power supply to more sophisticated models with the hand held device controlled via a digital control panel, which is used to control the speed of the needle.

### Design of equipment

65 Various models may have very different configurations of how they are assembled. However, there is a basic design that is common to many of the machines available in the UK:

- Needle -should be **disposable [single use only] in all cases;**
- Needle housing / cap / tube - is **in direct contact with the client's skin and should be disposable [single use only] in all cases;**
- Transmission shaft / needle bar; connects motor drive to the needle - can become heavily contaminated with used pigment and should be single use only in all cases where equipment design allows replacement;
- Needle sleeve / barrel - may consist of more than one tubular section – plastic sections are inexpensive and many are designed to be single use only; metal versions are available for some models and can be re-used with appropriate cleaning / disinfection or cleaning / sterilization;
- Motor interface / protective plate – part of the re-used section of the instrument; protects motor;
- Electrical motor;
- Outer motor casing – a re-used section; houses the motor and cannot be fully submerged;
- Power supply; and
- Speed control

66 The incorporation of single use / disposable parts, or parts that are capable of being re-used after steam sterilization, varies between manufacturers. The main reason why some equipment cannot be steam sterilized is that the motor is integral within the body of the equipment or that the plastic may be heat sensitive.

67 All parts of equipment that come into direct contact with the needle / shaft of the needle should be single use only or capable of being thoroughly cleaned then autoclaved.

68 The design of some equipment allows pigment - and hence potentially infected body fluids - to track back from the needle into parts of the equipment that are not disposable and not easily cleaned. The potential for internal fine droplet contamination within hollow equipment also exists, and has been acknowledged during scientific evaluation by German equipment manufacturers.

69 During HSE / LA investigations, equipment was found in use that was not single use and not capable of being steam sterilized, since parts of the main body of the equipment were plastic or the motor was contained within. It has therefore been necessary to produce a combined cleaning and disinfection method that allows equipment within this category to be used safely. (Appendix six details this method.)

70 To achieve effective disinfection of equipment that cannot be steam sterilized, re-used parts of the equipment must first be cleaned using an ultrasonic bath. This step removes any debris that may be on the equipment. The 5 stage cleaning method detailed in Appendix six incorporates ultrasonication. If followed correctly, it should allow such equipment to be

used without risk of cross contamination between clients.

### Prohibited equipment

71 Any equipment, which has parts that:

- May become contaminated with pigment during use; and
- Are regarded as re-usable, but are not capable of being steam sterilized; or
- Are regarded as re-usable but are not able to withstand the following 5 stage cleaning method;

has been prohibited from further supply if the HSE is aware of it.

72 If equipment, which falls into the above category, is found still in use it must be prohibited from any further use. **A typical example of a prohibition notice that might be served in this context is provided in Appendix 14. (LAU closed document version only).**

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## Appendix 6: five steps to achieve equipment disinfection

73 The following 5-stage disinfection method was developed in consultation with independent, recognised experts. Used needles, needle covers and needle bars should always be single use only. In many cases, plastic lower sections of equipment will also be single use only. If followed correctly, the remaining parts of the equipment – usually those housing the motor – can then be cleaned and disinfected, and can then be re-used without risk of cross contamination between clients. The following process must be repeated after each client use and before next use of the equipment:

1. Any **non-replacement part** of the equipment that has or may have become contaminated must be partially submerged, i.e. to cover all contaminated regions, in an ultrasonic bath containing an appropriate ultrasonic cleaning solution.
2. The cleaning solution should be made up and used in accordance with the manufacturers instructions.
3. The equipment must be rinsed in clean water following ultrasonication.
4. The equipment must then be immersed in a disinfectant*. It is important that the following are considered when carrying out disinfection procedures:
   a. Parts should be immersed for the correct contact time; the manufacturer of the disinfectant will recommend this time.
   b. Affected parts should be fully covered in the disinfectant.
   c. The disinfectant must be fresh and used at the correct concentration
5. Finally, the equipment must again be adequately rinsed in clean water to remove all chemical residues and then dried using a clean, single use, disposable paper towel.

*NB. The disinfectant must be capable of killing bacteria and blood borne viruses including, hepatitis B, hepatitis C, and HIV. The HSE does not recommend specific brands of disinfectant for this purpose, but commercially available disinfection products are available from companies such as Trigene and Steris. Further independent advice is available from the Health Protection Agency [9]

.

74 Only instruments that can tolerate ultrasonication should be processed in this way and equipment manufacturers should be approached directly to confirm this.

75 Operators should also check with manufacturers that any cleaning / disinfection agents used will not corrode or

damage the surfaces of their instruments.

76 Some practitioners use protective tape or transparent film over the outside of their instrument during each use, then dispose of this between clients. For surface disinfection 70% alcohol is effective, or any other disinfectant, such as chlorhexidine, in 70% alcohol. This procedure may reduce external surface contamination of equipment, but does not replace the need for cleaning, as described above. Sticky tape may also leave adhesive residues that may accumulate if not removed with suitable cleaning agents. Such residues should be avoided. Any peripheral external surfaces of equipment that are not submerged as described must therefore be wiped over with a suitable disinfectant between clients. The disinfectant used must be effective against blood borne viruses (HIV, hepatitis B, hepatitis C), and common pathogenic bacteria.

77 Washing up type gloves and eye protection should be worn when manually washing instruments.

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## Appendix 7: waste disposal

### Clinical waste

78 The Health Services Advisory Committee (HSAC Working Group), in agreement with the Advisory Committee on Dangerous Pathogens (ACDP), have produced a document entitled - The Safe Disposal of Clinical Waste (1999) (See Relevant Publication section for further information.). Clinical waste is currently defined as 'any waste consisting wholly or partly of human or animal tissue, blood or other bodily fluids, excretions, drugs or other pharmaceutical products, swabs or dressings, or syringes, needles or other sharp instruments, being waste which unless rendered safe may prove hazardous to any person coming in to contact with it'.

79 In July 2005 the Hazardous Waste Regulations (England and Wales) replaced some parts of the Special Waste Regulations, and this introduced new definitions of hazardousness for infectious and pharmaceutical wastes. Wastes that contain substances containing viable microorganisms or their toxins, which are known or reliably believed to cause disease in man or other living organisms, are regarded as hazardous wastes (code H9 - infectious). Following a recent DH-led consultation exercise, clinical waste groups have been re-organised and any agreed changes will be published in the DH document, Safe Management of Healthcare Waste, and accessible via the DH Web site at www.dh.gov.uk/consultations
[10]
.

80 The disposal of clinical waste is controlled by the Environment Agency (EA). There is a duty on those producing the clinical waste to take reasonable steps to handle and look after it safely, and to ensure others licensed to perform this task dispose of it legally. It is usually disposed of in yellow clinical waste bags. Clinical waste must be kept apart from general waste in a dedicated, secure area and must only be disposed/removed from the premises to a licensed clinical waste incineration site by a contractor licensed under the Waste Management Licensing Regulations, 1994, with the EA. Clinical waste should be disposed of to receptacles that are labelled clinical waste and are designed to avoid hand contact (to avoid hand contamination). A tag / label should identify the source of any clinical waste to satisfy audit trail requirements. Guidance on how to assess the hazardous properties of waste can be found in Annex C of the EA guidance document WM2, last updated in November 2005 and available at: The Environment Agency [960KB]
[11]
. A further guidance review is planned in 2006-07.

### Sharps

81 Sharps should be disposed of in an approved sharps container, constructed to BS 7320 / UN 3291 1990, and must be disposed of through a waste management company who will dispose of them safely as category 'b' waste - for incineration only. The Environmental Protection Act (1990)

[12]
Waste management: the duty of care, a code of practise (ISBN 0 11 752557 X) gives further information on this subject.

Care should be taken to avoid accidental needle-stick injury, as exposure to contaminated blood may be associated with transmission of Blood Borne Viruses e.g. Hepatitis B, HIV. All staff handling sharps should undergo a course of hepatitis B vaccine. Vaccination and blood tests can be arranged through General Practitioners. A record of hepatitis B antibody response should be kept for all vaccinated staff where regular exposure to blood/blood stained body fluids occurs.

**82 Being 'sharps safe':**

- Clinical sharps should be single use only;
- Do not re-sheath a used needle;
- Sharps containers must comply with UN 3921 and BS7320 standards;
- Sharps containers should be available at each location where sharps are used;
- Discard sharps directly into a sharps container immediately after use and at the point of use, close the aperture to the sharps container when carrying or if left unsupervised to prevent spillage or tampering;
- Do not place sharps containers on the floor, window sills or above shoulder height – use wall or trolley brackets, they should be stored above knee level and below shoulder level;
- Assemble sharps containers by following the manufacturer's instructions;
- Carry sharps containers by the handle - do not hold them close to the body;
- Never leave sharps lying around;
- Do not try to retrieve items from a sharps container;
- Do not try to press sharps down to make more room;
- Lock the container when it is three-quarters full using the closure mechanism;
- Label sharps containers with the source details prior to disposal; and
- Place damaged sharps containers inside a larger container - lock and label prior to disposal - do not place inside yellow clinical waste bag.

Blood spillage is unlikely during tattooing-related treatments due to the limited depth of needle penetration. However, bleeding or loss of blood products from treated areas may occur and can be safely treated as follows:

- The operator must put on gloves (nitryl, latex or vinyl – approved for use with biological agents) if not already wearing them;
- Stop the bleeding by applying pressure to the wound with a dry sterile dressing;
- Dispose of dressing into yellow clinical waste bag; and
- Replace the sterile dressing.

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## Appendix 8: anaesthetics

### Information relating to The Medicines Act (1968); The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980

83 Pain thresholds vary between individuals. Therefore anaesthetics are sometimes used. The Medicines Control Agency (now part of the MHRA) is the main enforcement body of the Medicines Act 1968, which sets out the general rule that most medicines may only be sold or supplied through pharmacies. Medicines sold are divided into three main groupings:

a. **Prescription only medicines (POM)**, supplied by, or under the supervision of, a pharmacist following an appropriate practitioner's prescription, e.g. Doctor, dentist, or under certain circumstances, an independent nurse prescriber or supplementary prescriber.

b. **Pharmacy medicines (P)**, supplied only by, or under the supervision of, a pharmacists and under supervision from a pharmacist.

c. **General sales list medicine (GSL),** available from other retail outlets

To this end, it is important to note that in the UK **any** medicinal product that is injected is classed as POM and as such, if not self administered; should be administered by a doctor or, in certain circumstances, by an independent nurse prescriber or supplementary prescriber. Injectable medicine can also be administered by anyone acting in accordance with patient-specific directions of a doctor or again, in certain circumstances, by an independent

- nurse prescriber or supplementary prescriber;
- The use of a POM would be inappropriate unless the client's doctor had prescribed it;

Lignocaine-based cream/spray and Ametop gel are (P)-products. They can be legally used as topical anaesthetics by the Purchaser, (including a tattooists or body piercers) but they must not be administered by

- injection, as this will make the products POM;

Ethyl chloride, a (P) issue drug, should be avoided – Resulting skin damage may increase the chances of

- infection at the treated site;

Under the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, the actual sale and supply of (P)-products is allowable for certain businesses. The person owning such a business can buy these medicines wholesale if they qualify as requiring their administration in the course of a business carried on by him, and they are to be used within their licensed indications. Further clarification is available from section 130 of the

- Medicines Act, 1968; and

The Medicine Controls Agency or police should be informed if any **P** or **POM** drugs are prescribed or sold without license or if either is used inappropriately. General referrals can be directed to the Enforcement Section of the

- Medicines and Healthcare products Regulatory Agency, Tel. No: 020 7o84 2330.

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## Appendix 9: pigments

84 There are many different types of pigment available from many different suppliers. It is essential that pigments be:

- Purchased from reputable suppliers
- Supplied with data sheets stating metal impurities/sterility

Dispensed into one use only containers, i.e. that are used for only one client. Ideally, these should be pre-packed and sterile. If not sterile, the level of cleanliness before use should be at a level comparable to that

- achieved for disinfected hand piece components.
- Appropriate for their use, i.e. cosmetic or body art.

85 Other relevant considerations include:

Micropigments are physically different to tattooing inks in that they are made from suspended particulates in a

- liquid base, traditional tattooing dyes or inks comprise fully soluble colours;

Descriptions of micropigment content as ‘natural plant extracts’ or ‘natural products’ are no guarantee that the pigment will fade within timescales quoted by operators, or that it will be chemically and biologically appropriate

- for intradermal administration;
-

Concerns remain over the degree of permanence of temporary or semi-permanent tattoos, i.e. products are variously described as having an effective life of between 1 and 'several' years. Many commercial UK Web sites offering such treatments are not specific about the longevity of the treatments they provide. Since most UK treatments will have been administered within the last 5 years, the degree of permanency of the many available

- products is not yet clear; and

**Anecdotal evidence from the Tattooing and Piercing Industry Union suggests that 'temporary tattoos' usually last far longer than clients are led to believe. The TPI also state that any attempts to over-tattoo**

- **unwanted old tattoos, using skin coloured pigment, is generally an unsuccessful way to eliminate them.**

86. Since the original publication of this guidance in December 2003, a number of commercially available pigment products have been microbiologically tested at a Government laboratory and some found to be contaminated with environmental bacteria and fungi. Pigment analyses were undertaken on products from three suppliers, and all tests involved the use of previously unopened products. Bacterial levels in the order of $10^5$ bacteria/ml were detected in three products from one supplier, with fungal levels in the order of $10^2$ fungi/ml in another product from the same supplier. This level of contamination is unacceptable for a product that is designed for skin injection, and for this reason EHOs and operators should seek evidence for product sterility prior to their use on the client. Microbiological safety tests can be carried out by most public health / hospital laboratories. Also related to pigment sterility is the use of water for diluting pigments prior to treatments. This is a known technique for thinning colours, but carries a risk of pigment contamination if the water is not sterile. The ideal product for any such dilution would be 'water for injection, B.P.' because it is guaranteed sterile. However, water for injection, B.P is a 'Prescription-only' medicine because it is designed specifically for injection purposes, and as such it is not freely available for purchase by the public. Other sterile water products are commercially available, but these are not sold for injection. The temptation to use a cheaper, bulk water supply and to then prepare aliquots should also be avoided, as this can lead to contamination. The lack of general availability of Water for Injection, BP means that no safe and appropriate supply can be recommended for pigment dilution. If in doubt, advice from a high street pharmacist should be sought.

87. **Henna** has been widely used as a temporary skin pigment for thousands of years, and is still popular amongst those wanting a painless and temporary tattoo. Henna acts as a dye because it contains hydroxy-naphthoquinone, also known as lawsone, which stains the skin. Traditionally applied henna tattoos last only 2-3 weeks due to their topical application on to the outer epidermal layer of the skin, usually as a paste. However, complications have been widely reported following the addition of para-phenylenediamine (PPD), which can darken the pigmentation and make it longer lasting (Raison-Peyron *et al.*, 2000; Pegas *et al.,* 2002). Recent Government laboratory tests on the composition of a henna product were performed for a local authority. The product was obtained from a mobile operator, had been imported from Israel, and was found to contain no detectable henna. However, it did contain 94% PPD, and since some individuals are known to be sensitive to PPD, even at low concentrations, the presence of a large amount of PPD in a tattoo product is inappropriate. Puncturing of the skin may increase exposure and exacerbate allergic response to PPD in henna, and is a practice performed by some operators seeking longer-lasting results from henna tattooing.

88. It is essential that materials injected intradermally using micropigmentation machines, e.g. pigment, ink or pigment removal products, must be supplied with supporting paper work to demonstrate product purity and suitability for injection. Information supplied with the product should include laboratory test data that confirms the product is free of microbiological contaminants and toxic metals such as Nickel, Cadmium, Chromium and Lead. If there is any doubt about a product's purity, or its suitability for intradermal injection, then contact must be made with the product manufacturer to determine if such test data are available. If an end user cannot obtain such reassurances in writing then use of the product should be avoided, at least until product safety is confirmed by chemical and microbiological testing in an appropriate laboratory.

### Pigment (tattoo) removal

89. In the past, the removal of tattoos has typically involved the use of progressive skin (derm)abrasion or laser-based

light treatments, both of which are usually carried out in specialist private clinics or hospital departments. Dermabrasion literally rubs the tattooed skin away with an abrasive tool, over a series of treatments. If the tattoo is deep, a skin graft may also be necessary to 'level out' the surface of the skin. Laser therapy is therefore the more favoured of the two approaches and works by penetrating the skin and producing a change in the pigment composition that leads to pigment removal by the body. The pigments are eventually removed by the lymphatic system. Different wavelengths of light are used for different coloured pigments in order to achieve this outcome, and a series of treatments is usually needed. Laser therapy has been confirmed as effective for tattoo removal and the process has been medically evaluated and reported following a 9-year study (Reid *et al.,* 1990). Laser removal is generally considered to be a safe procedure, and is usually performed as an outpatient procedure under a local anaesthetic (which numbs the area immediately around the tattoo), so the client should not feel pain. However, scarring and incomplete removal can occur.

Also from the EC-funded report, Risks and Health Effects from Tattoos, Body Piercing and Related Practices [95KB] [13]. Habia have also produced a training document entitled Safe Use of Lasers and Intense Pulse Light Equipment [856KB] [14], which provides useful background on tattoo removal using lasers.

90. Alternative **chemical tattoo removal treatments** have gained in popularity over recent years, with commercial treatments now marketed in the UK. These treatments require multiple intradermal injection of a chemical removal system, in much the same way as the pigment was initially inserted. A tattooing / micropigmentation instrument is used, and identical infection control precautions must therefore be applied, as used for pigment insertion. Concerns have been raised over the safety of such treatments (Veysey & Downs, 2004). The mechanism of action for chemical removal treatments is uncertain, but at least one manufacturer states that the action is due to the product's high affinity for tattoo pigments of all types, allowing it to blend well with the tattoo pigment and so facilitate tattoo mobilisation from the skin (Cheng, 2004). Components of the this particular system are reported to include de-ionised water, zinc oxide, magnesium oxide, calcium oxide, isopropanol, triethanolamine and benzoic acid; chemicals described by the manufacturer as listed in the International Cosmetic Dictionary. The manufacturer's own studies report 0% scarring after treatment of cosmetic facial tattoos, and 6% scarring after treatment of body tattoos (of 98 clients studied). From these studies, Cheng (2004), also describes the rate of adverse events as <1% for trained operators, but acknowledges that good training and experience of tattooing or micropigmentation is recommended for successful tattoo removal.

91. An alternative tattoo removal system available in the UK is described by its manufacturer as one where, *The top of the skin is treated in a series of dots in a similar way to how the tattoo was put in, using a needle. Instead of ink however a natural product is used. This product encourages the body to expel the pigment of the tattoo, similar to how the body expels a splinter.* The manufacturer's web site offers no further information on product composition though information provided by an LA enforcement officer who has spoken to a Tattoo Erase user has confirmed that a key ingredient is lactic acid (lactate). The concentration of lactate at point of use is uncertain. If lactate is a component of a tattoo removal system then users should be aware of the possible adverse health effects that can result from its injection. Lactate can be found naturally within the body, but if inadvertently injected in to the blood, only a small increase can result in physiological disturbances (Sharma *et al.,* 2004). Localised tissue injection of lactate as low as 10% is reported to be damaging to mammalian tissues (Fordyce *et al.,* 1989; Pomorski *et al*., 2002), and operators must therefore be certain of the safety of chemical ingredients before use. This should be made clear within accompanying product data sheets, but if uncertainty exists about the safety of any chemical component of an injected product, then advice should be sought from a pharmacist or GP. Because any chemical tattoo removal procedure also involves puncturing of the skin in a way similar to that used for pigment insertion, all previously described hygiene precautions must be observed.

92. The Local Government (Miscellaneous Provisions) Act, 1982, does not give local authorities powers to regulate tattoo removal. For this reason licensing and enforcement of chemical tattoo removal activities remains an area of uncertainty for environmental health officers. However, the Health and safety at Work Act, 1974, will apply. In summary, surgical or

laser removal of tattoos by trained personnel, (surgeons, or trained laser technicians), have been evaluated and shown to be effective for tattoo removal. For many, these will remain the treatments of choice, until such time as other methods - including chemical removal systems - have been independently evaluated for safety and efficacy.

### Use of micropigmentation within the health care sector

93. Reports from the HSE suggest that micropigmentation instruments are now being used widely within the health care sector for corrective, cosmetic procedures, including scar camouflage and post-operative nipple (areolus) pigmentation following breast surgery. It is likely that, just as on the high street, there is a range of machinery in use, though information in this area is scant. The use of such machines includes both NHS and private clinics, and the nature of the treatments is quite distinct from most typical cosmetic (adornment) treatments performed by the high street operator. Since most of the past advice related to micropigmentation was aimed at high street businesses, there is concern that hospital based users – usually doctors or nurses – may be unaware of the unique infection control problems associated with equipment. In order to raise awareness of the required cleaning procedure and other information supplied within this document, a bulletin has been placed on the web site of the Infection Control Nurses Association to raise awareness within this sector.

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## Appendix 10: enforcement

For HSWA issues, any enforcement action should be in accordance with the Commission's Enforcement Policy Statement and, in particular, with the principle of proportionality, i.e. action proportionate to the risk arising from the breach.

94. **Action to take**

- Where you receive information that micropigmentation is taking place, which may involve the use of a machine suspected of presenting a cross infection risk, investigate to determine whether the standards referred to in this LAC are being achieved. Where they are not, then enforcement action may be required.
- Inform Local Authority Unit (LAU) / Enforcement Liaison Officer (ELO) of any enforcement action you are contemplating that is a **new** development, i.e. LAU need not be informed every time enforcement action is required.
- If you require specialist support from HSE contact your ELO

95. **Enforcement action should be taken if equipment does not have**:

- An appropriate CE mark
- A declaration of conformity
- Adequate cleaning instructions

96. **Information should be passed to the HSE via your ELO** with equipment that has parts that can be potentially contaminated with pigment or body fluids either by:

- Tracking back, or
- Aerosol contamination

97. **Parts should be:**

1. Single use (disposable); and / or
2. Able to be sterilized by steam sterilization; and / or
3. Capable of undergoing the 5 stage cleaning method or equivalent

98 **If not, a Prohibition Notice should be served, until it can be demonstrated that the contaminated part(s) can be effectively cleaned. This is because of the risk of serious infection that may result from re-use of contaminated equipment if cleaning cannot be carried out effectively.**

99 **The HSE should be informed, via your ELO, as the design of the equipment or the instructions may need to be addressed under the Product Supply legislation.**

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## Appendix 11: website links

- Health and Safety Executive [15]
- Department of Health [16]
- The National Health Service [17]
- Health and Beauty Industry Association [18]
- American Academy of Micropigmentation [19]
- Tattooing and Piercing Industry Union [20]
- Qualifications and Curriculum Authority [21]

### Relevant publications


- **Protection against blood-borne infections in the work place: HIV and hepatitis**, (Advisory Committee on Dangerous Pathogens). HMSO 1996, ISBN 0 11321953 9
- Blood-borne viruses in the workplace: guidance for employers and employees [103KB] [22]
- . HSE booklet - INDG 342
- **Cheng, W.** (2004). Chemical extraction technique for tattoo removal. Br. J. Dermatol. **151**; 1272–1288
- **Immunisation against infectious disease** 1996 HMSO, ISBN 0 11 321815 X.
- HSE online guidance on alternatives to latex gloves [23]
- due to the high incidence of allergy reported by wearers.
- **Body art, cosmetic therapies and other special treatments**: Barbour Index: CIEH:ISBN 1-902423-80-1
- Benchtop steam sterilizers - guidance on purchase, operation and maintenance [595KB] [24]
- : Medical Devices Agency, Device Bulletin 2002(06) October 2002.
- **Fordyce G., Hodge P.B., Beaman N.J, Laing, A.R., Campero, C. and Shepherd, R.K.** (1989). An evaluation of calf castration by intra-testicular injection of a lactic acid solution. Aust Vet. J. **66**(9); 272-6.
- **Local Government Act 2003**: Regulation of cosmetic piercing and skin-colouring businesses – guidance on Section 120 and Schedule 6 [25]
- (Department of Health)

MHRA-MDA document DB2000(04). Single-use Medical Devices: Implications and consequence of Re-use [26]

- .
- **MHRA-MDA document SN2001(19)**. Safe use and Disposal of Sharps.
- **Natural rubber latex sensitisation** in health care. HSE Field Operations Directorate document SIM 7/2003/24
- **NHS Estates.** (1997). Washer-disinfectors, Validation and Verification. Health Technical Memorandum HTM2030. Stationery Office Books. ISBN: 0113220715
- **Norman Noah**: Guidance on Micropigmentation. Unpublished document but available on request from the author at Norman.noah@lshtm.ac.uk

Norman Noah [27]

- . 2006. Tattooing and piercing – the need for guidelines in EU. Euro Surveill. 2006;11(1).
- **Pegas JR, Criado PR, Criado RF, Vasconcellos C, Pires MC.** (2002). Allergic contact dermatitis to temporary tattoo by p-phenylenediamine. J. Investig. Allergol. Clin. Immunol. **12**(1):62-4.
- **Pomorski L, Bartos M, Matejkowska M, Kuzdak K**. (2002). The influence of a single acetic acid and lactic acid injection on rat normal thyroid tissue. Cesk Patol. **38**(3):107-12.
- **Raison-Peyron N, Meunier L, Vian L, Meynadier J.** (2000). Contact dermatitis caused by labile henna skin tattoo. Ann. Dermatol. Venereol. **127**(12):1083-6.
- **Reid WH, Miller ID, Murphy MJ, Paul JP, Evans JH.** (1990). Q-switched ruby laser treatment of tattoos; a 9-year experience. Br. J. Plast. Surg. **43**(6):663-9.

**Sharma, S. MD, FRCPC.** (2004). Lactic Acidosis [28]

- .
- **Spear SL, Arias J.** (1995). Long-term experience with nipple-areola tattooing. Ann. Plast. Surg. 35(3):232-6.

The Pressure Systems Safety Regulations 2000 [29]

- . See also: HSE Approved Code of Practice Safety of Pressure Systems (L122) - ISBN 0 7176 1767 X.
- **The safe disposal of clinical waste** -The Health Services Advisory Committee (HSAC Working Group), in agreement with the Advisory Committee on Dangerous Pathogens (ACDP), 2nd Edition (1999). HSE Books, ISBN 0 7176 2492 7
- **Veysey E. and Downs, AMR.** (2004). Adverse side effects following attempted removal of tattoos using a non-laser method. Br. J. Dermatol. **150**: 770–1.
- Waste management: the duty of care, a code of practice - The Environmental Protection Act (1990): ISBN 0 11 752557 X.

**J Worp, A Boonstra1, RA Coutinho, JAR. van den Hoek.** (2006). Tattooing, permanent makeup and piercing in Amsterdam; guidelines, legislation and monitoring [30]

- . Euro Surveill. 2006;11(1).

## Appendix 12: micropigmentation inspection checklist

This list is not exhaustive, but may act as an aide-memoir during premises visits

- Registration
- Records available

- Consent forms or other related client records, e.g. photographic
- COSHH Assessments
- Written aftercare guidance for clients
- Training records of operators
- First aid training
- Blood (body fluids) spill kit
- Operator hepatitis B immunisation
- Public liability insurance

  Hygiene measures, including:

  - Designated wash hand basin for operators only
  - Liquid dispense soap
  - Hot and cold running water
  - Disposable paper towels
  - Procedures for cleaning work surfaces
  - Procedures for cleansing client's skin

    Disposable nitryl/vinyl gloves with Microbiological Hazard Group 2 CE marking (latex gloves should be avoided as they are associated with latex allergy

    [31]
  - )
  - Disposable plastic apron
  - Disposable paper sheets for treatment couch
  - No smoking sign
- - Needles: Pre-sterilized disposable needles / needle covers / needle bars
- Types of topical anaesthetics
- Sharp box
- Sharps box disposal
- Clinical waste disposal
- Micropigmentation equipment type and ease of safe re-use
- Work surface – type / ability to clean
- Ultrasonic cleaner
- Frequency of ultrasonic solution changes – type / suitability
- Disinfectants used – type / appropriate biocidal activity
- Autoclave sterilization procedures / daily records sheet
- Autoclave performance test certificate

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This appendix is for enforcing authorities only

# Appendix 13: photographs and details of known equipment

The following is a summary of known equipment and the findings of an investigation of availability and suitability for purpose of micropigmentation machines within the UK.If equipment is found that is not detailed in the table then action should be taken according to the advice given in Appendix **Ten** "Enforcement".Where possible below, a logical split of equipment has been indicated to reflect three main groupings:1. Those prohibited or withdrawn from supply to date because the are not fit for purpose in terms of their microbiological safety; 2. Those which, although not State of the Art, can be used with the 5-step cleaning protocol, and 3. Those that are safe by design, or can undergo steam sterilization, or have fully disposable parts in areas that may become contaminated.4. Any machine for which only limited information is available.**NB.** Even equipment of good design, where identified, must be handled in line with the manufacturer's instructions.

## 1. Prohibited instruments or instruments that have been voluntarily withdrawn from use / supply by the manufacturer

**Goldeneye Basic**

The Goldeneye Basic could not be effectively cleaned, in that internal areas, which may become contaminated, were inaccessible for effective cleaning and disinfection. All persons supplied with the Goldeneye Basic were contacted to ensure that its use was withdrawn.

**Enforcement**

If found being used on premises a Prohibition Notice should be served

**Reza**

This information relates only to 'old' Reza equipment in production before November 2003:The needle and cover are disposable. The chuck is removable and capable of being steam sterilized. It appears that the inside of the hand piece cannot be cleaning by ultrasonic bath, as manufacturer is re-designing the hand piece. Equipment was voluntarily withdrawn on 10/6/03, pending arrival of new hand piece called Reza Euro. The newly modified hand piece was scheduled for sale from November 2003.All known users of the 'old' equipment have been informed that it should not be used until the replacement hand piece has been provided.

**Enforcement**

If the old Reza instrument is found still in use a Prohibition Notice should be served.

**Tsai Yi**

This equipment is not capable of being effectively cleaned due to the design of the needle housing bar and its interface with the motor, which may become contaminated with pigment and hence body fluids.As the equipment is no longer being supplied in the UK a Prohibition Notice was not served. All those who purchased the equipment have been contacted to ensure that it is no longer used. Recent on-line searches have shown that this instrument is still being sold overseas.

**Enforcement**

If equipment is found in use then a Prohibition Notice should be served.

### 2. Instruments that can be cleaned by the HSE 5-step disinfection procedure or by other (demonstrated) acceptable means

**Carole Franck**

This equipment has a plastic disposable probe, which contains the needle. This is housed in a stainless steel holding pen. The holding pen is smooth and easy to clean. The holding pen and its internal parts can be cleaned in accordance with the HSE cleaning guidance.

**Elite 2000**

*No image available at time of writing*

This equipment has a disposable needle bar, needle and sheath. It also has a detachable metal hub that can be cleaned in accordance with the HSE cleaning guidance. The metal hub encloses the connection of the needle bar to the motor. The motor unit is fully enclosed and sealed therefore nothing can track back.

**Giant Sun**

All parts of the equipment from the transmission shaft forward of the needle and cap are disposable. The motor is sealed and therefore the equipment can be cleaned in accordance with the HSE cleaning guidance, however only up to where the power plugs into the machine.

**Goldeneye Liner 1**


There are few, if any, Goldeneye Liner 1 models known to be in operation, as the Golden Eye Liner 4 has superseded this model. Contaminated parts are either disposable or can be effectively cleaned in

accordance with the HSE cleaning guidance. O-rings must be removed during the cleaning procedure to avoid accumulation of pigment residues in the O-ring seating.

**Goldeneye Liner 4**

 This model has replaced the Goldeneye Liner 1 models. It has been improved in design in that the needle has a fused on needle base that completely covers the underlying thread. The plastic needle base is concave on the needle side to catch any liquid that may track back. Two O - rings prevent any tracking back of pigment and are tightly hugged by the plastic tip once it is in place. The O - rings should be removed during ultrasonication and the instrument tip can be immersed up to the groove of the second O-ring. The O -rings can also cleaned in the ultrasonic bath. However they are inexpensive, readily available from the manufacturer and best practice would be replacement between clients.

**Long Time Liner**

 Currently, there is no known supplier of this equipment within the UK and the focus of business appears to be in Germany. The equipment was sold in the UK up until ~4 years ago. The manufacturer has been contacted and has confirmed that it is possible to clean the equipment in accordance with the HSE cleaning guidance.

**Mei-Cha – Sapphire Dynasty 2000**


 All parts are disposable except the top-end motor housing. Initial examination of literature supplied by the overseas manufacturer indicated that the equipments should not be turned upside down, as tracking back of the pigment may occur. The UK supplier has since established that the HSE 5-step cleaning regime can be applied to this instrument, making the machine hygienically safe for re-use, providing these cleaning steps are implemented.

**Mei-Cha – Platinum 6000**

 All parts are disposable except the top-end motor housing. The manufacturer confirmed in 2004, via the main UK supplier, that re-used parts of this machine could be cleaned using the HSE 5-step cleaning method, making the machine hygienically safe for re-use, providing these cleaning steps are implemented.

**Merlin from Bio Touch**



All parts are disposable except the top-end motor housing. The top end motor housing has no difficult recesses. If training, instructions and controls are followed there is a very low risk of cross contamination. In 2003 users of this instrument informed HSE that re-used parts could be partially submerged for the purpose of ultrasonication.The plastic needle cover on this instrument has a side aperture that allows side loading of pigment, but laboratory testing has shown that this can result in a greater degree of tracking back of pigment during use. Tip loading is therefore a more controlled and preferable method for loading pigment on to the needle of this instrument.

**Pure Beau**


The manufacturer has indicated that the TRS 250 Pure beau equipment can be cleaned using the HSE 5-step cleaning procedure. In November 2004 the manufacturer also indicated that it would amend all literature that accompanies its UK distributed instruments so that hygiene requirements for the end user were given more emphasis.

**Seeme**



The needle, needle guard and a removable grip are all available as single use, disposable items. The device is supplied with a metal grip, which is capable of being autoclaved. Risk of cross contamination is extremely small if disposable items are used and metal grip is autoclaved properly after use.

**Softap**


Softap products are non-motorised and comprise of a holder and choice of needles. The holder is autoclavable and the needles are sterile and disposable (one use only). Also available is a disposable all-in-one hand tool, which is sterilized and wrapped like a disposable syringe. The whole unit is disposed of after each use.

**Starlight**



Needle bar, needle and sheath are disposable, (and are transparent to aid visible detection of tracking back.) The supplier has confirmed that the equipment can be cleaned in accordance with the HSE cleaning guidance.

**Starlight California**


Manufacturer's instructions supplied to HSE for comment in July 2004 indicated that this equipment could be cleaned using the HSE 5-step cleaning procedure.

**Sunshine**



All parts of the equipment from the transmission shaft forward of the needle and cap are disposable (one use only). The motor is sealed and therefore the equipment can be cleaned in accordance with the HSE cleaning guidance. However, submersion must not be taken as far as the point where the power plugs into the machine.

### 3. Instruments that are safe by design

**LCN**

The needle and holder comprises one complete disposable unit (called "hygiene unit"). There is a shaft protruding from the top end of the "hygiene unit" that connects with a recess in the motor unit. The motor unit surrounds the shaft when the cartridge is in place. An internal membrane within the "hygiene unit" means that there is no effective opening between the needle and the motor, and this prevents tracking back of pigment.The outer surface of the hand piece must still be cleaned between clients.

**Noveau Contour**


This equipment uses a similar design principle to that of the LCN, and the disposable

needle cartridge contains an internal seal to prevent back tracking of contaminates up the hand piece.The outer surface of the hand piece must still be cleaned between clients.

**Medium Tech**

The needles and needle cap are included in one disposable cartridge. This cartridge is securely sealed by a membrane, which protects the hand piece from internal contamination. The outer surface of the hand piece must still be cleaned between clients.

## 4. Instruments for which only limited information is currently available

**The Princeton Machine**

Other than the ability to unscrew the top sections, nearest the chrome-ringed motor, there seems to be no facility to dismantle the lower sections that surround the length of the needle on this machine. As a result, there appears to be no way that this instrument could be cleaned properly internally, or examined internally to ensure it was clean.

In addition, the needle cannot readily be removed from the machine, and the brief user instructions provided were poor and gave no indication of how to remove the needle. The user instructions also failed to describe how to clean the machine between clients; particularly important here in view of the inability to dismantle the hand piece fully.

Although further enquiries are in progress in relation to this machine, direct observations already suggest it is unlikely that the Princeton machine can be cleaned and disinfected reliably using the HSE 5-step method.

**Spaulding and Rogers Revolution**

This instrument is known to be in use within the Health Care Sector, West Midlands. All attempts by hospital users and HSL / HSE to contact the US manufacturer / supplier have failed, and no detailed hygiene information is available from the manufacturer. All replaceable items on this machine must be regarded as one use only and replaced new for each client. In particular, this applies to the needle / needle bar. The hollow hand piece must be effectively decontaminated and steam sterilized between clients. If the instrument is used frequently then multiple hand pieces must be available to allow use of a sterile hand piece for each new client, while used hand pieces are decontaminated and steam sterilized ready for re-use. The whole motor area must be completely wiped over with an appropriate disinfectant wipe between clients. Particular attention must be paid to the recessed regions where the hand piece and the needle bar insert in to the motor body. This instrument would appear fit for purpose and unlikely to promote

cross contamination of pigment / blood products between clients. However, safe use would only be maintained if the described decontamination and sterilizing steps were strictly applied.

## Appendix 14 - This appendix is for use by enforcing authorities only

### Sample prohibition notice for equipment that cannot be cleaned

**xxx METROPOLITAN BOROUGH COUNCIL** **Serial No.P/**

Health and Safety at Work etc. Act 1974, Section 22,23 and 24

| | | |
|---|---|---|
| | **Name:** | |
| | **Address:** | |
| | **Trading as:** | |
| **Inspector's full name and official designation** | I, **xxxxxxxxxxxxxxxxxxxx** one of **xxxxx xxxxxxxxxxx** Council's Environmental Health Officers being an Inspector appointed by an instrument in writing made pursuant to Section 19 of the said Act and entitled to issue this notice. | |
| **Official address** | of **xxxxxxxxxxxxxxxxxxxxxx, xxxxxxxxxxx, xxxxxx Street, xxxxxx, xxxxxxx.** Telephone number **(xxxxx) xxxxxx** extension **xxx** hereby give you notice that I am of the opinion that the following activity, namely: **the use of the xxxx micropigmentation hand piece, serial number xxxx** | |
| | | |
| **Location of premises or place of activity** | which is being carried on by you/likely to be carried on by you/under your control* at **xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx** | |
| | involves, or will involve, a risk of serious personal injury, and that the matters which give rise/will give rise* to the said risk(s) are: **the potential for the transmission of blood borne viruses including human immunodeficiency virus (HIV), hepatitis B and C between clients undergoing micropigmentation procedures with the said xxx micropigmentation hand piece**<br><br>and that the said matters involve/will involve* contravention of the following statutory provisions:<br><br>**Health and Safety at Work etc. Act 1974, Section 3 (1)**<br><br>**because you have failed to ensure so far as is reasonably practicable, that persons not in your employment who may be affected thereby are not exposed to risks to their health or safety in that the hand piece of the xxx machine could become contaminated with body fluids and thus blood-borne viruses during use and it is not designed and constructed to permit effective cleaning and disinfection between use on different clients**<br><br>and I hereby direct that the said activities shall not be carried on by you or under your control immediately unless the said contraventions and matters have been remedied. | |
| | | |
| | Signature | Date: |
| | *A Prohibition Notice is also being served on | |
| | of | |
| | related to the matters contained in this notice. | |
| | | |

| | | |
|---|---|---|
| Environment and Safety Information Act 1988 | This is a relevant notice for the purposes of the Environment and Safety Information Act 1988. **YES** | |
| | This page only will form the register entry* | |
| | Signature | Date: |
| | *Delete as appropriate | See Notes Overleaf |

**SAMPLE PROHIBITION NOTICE FOR EQUIPMENT THAT IS NOT BEING CLEANED EFFECTIVELY**

**HEALTH AND SAFETY AT WORK ETC. ACT 1974,** Ref. No.
Sections 22,23 and 24

# PROHIBITION NOTICE

Name: **xxxxxxxxxxxxx**

Address: **xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx**

Trading as: **xxxxxxxxxxxxxxxxxxxxxxx**

I, **xxxxxxxxxxxxx**, being an Inspector appointed by an instrument in writing made pursuant to section 19 of the said Act and entitled to issue this notice

of **xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx.**

Telephone number: **xxxxxxxxxxxxxxxxxx** hereby give you notice that I am of the opinion that the following activity namely: **the use of the xxxx micropigmentation hand piece, serial number xxxx**

which is being carried on by you/likely to be carried on by you and under your control*

at **xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx**

involves, or will involve a risk of serious personal injury, and that the matters which give rise/will give rise* to the said risk (s) are: **the potential for the transmission of blood borne viruses including human immunodeficiency virus (HIV), hepatitis B and C between clients undergoing micropigmentation procedures with the said xxx micropigmentation hand piece** and that the said matters involve/will involve* contravention of the following statutory provisions:

**The Health and Safety at Work etc. Act 1974, Section 3 (1)**

**because you have failed to ensure so far as is reasonably practicable, that persons not in your employment who may be affected thereby are not exposed to risks to their health or safety in that the hand piece of the xxx machine could become contaminated with body fluids and thus blood-borne viruses during use and it is not being effectively cleaned and disinfected between use on different clients**

and I hereby direct that the said activity shall not be carried on by you or under your control immediately unless the said contraventions and matters have been remedied. I further direct that the measures specified in the schedule which forms part of this notice shall be taken to remedy the said contraventions or matters.

Signature: ……Date:

*A Prohibition Notice is also being served on **xxxxxxxxxxxxxxxxxxxxxxx**

of **xxxxxxxxxxxxxxxxxxxxxxxxxxxx**

related to the matters contained in this notice

This is a relevant notice for the purposes of the Environment and Safety Information Act 1988 **YES**

This page only will form the register entry*

Signature:……Date:

* delete as appropriate

***SCHEDULE***

**TO COMPLY WITH THIS NOTICE COMPLETE EITHER ITEM 1 OR ITEM 2:**

**1. Five Key stages to achieve equipment disinfection:**

i. All disposable parts must first be removed and disposed of safely, i.e. needles in approved sharps container.
ii. Any remaining part of the equipment that has or may have become contaminated must then be submerged, to cover all contaminated regions, in an ultrasonic bath containing an appropriate ultrasonic cleaning solution, made up and used in accordance with the manufacturers instructions. This will dislodge any debris to enable effective disinfection of the equipment in the fourth part of the cleaning process.
iii. The equipment must be rinsed in clean water.
iv. The equipment must then be immersed in a disinfectant, for the correct contact time (this time will be recommended by the manufacturer of the disinfectant). The disinfectant must be capable of killing bacteria and blood borne viruses including, hepatitis B, hepatitis C, and HIV.
v. The equipment must again be rinsed in clean water and dried using a clean, single use, disposable paper towel.

**Or alternatively,**

**2. Any other equally effective measures may be used to achieve the same level of cleaning and disinfection**

1. Failure to comply with this Prohibition Notice is an offence as provided by section 33(1)(g) of the Health and Safety at Work etc. Act 1974 and section 33(2A) of this Act renders the offender liable on summary conviction to imprisonment for a term not exceeding 6 months, or to a fine not exceeding £20,000, or both, or, on conviction on indictment, to imprisonment for a term not exceeding 2 years, or a fine, or both.
2. Except for an immediate Prohibition Notice, an Inspector has power to withdraw a notice or extend the period specified in the notice, before the end of the period specified in it. If you wish this to be considered you should apply to the Inspector who issued the notice, but you must do so before the end of the period given in it. Such an application is not an appeal against this notice.
3. The issue of this notice does not relieve you of any legal liability for failing to comply with any statutory provisions referred to in the notice or to perform any other statutory or common law duty resting on you.
4. You can appeal against this notice to an Employment Tribunal. Details of the method of making an appeal, a form to use, and information about where to send it are contained in booklet ITL 19 which will be provided by the inspector with this notice. Copies are also available from the Employment Tribunal Enquiry Line (Tel: 0345 959775).

## Time limit for appeal

A notice of appeal must be sent to the Employment Tribunal within 21 days from the date of service on the appellant of the notice, or notices, appealed against, or within such further period as the tribunal considers reasonable in a case where it is satisfied that it was not reasonably practicable for the notice of appeal to be presented within the period of 21 days. If posted, the appeal should be sent by recorded delivery.

The entering of an appeal does not have the effect of suspending this notice. Application can be made for the suspension of this notice to the Employment Tribunal, but the notice continues in force until a tribunal otherwise directs.

An application for suspension of the notice must be in writing and must set out: a) the case number of the appeal, if

known, or particulars sufficient to identify it; and b) the grounds on which the application is made. (It may accompany the appeal).

The rules for the hearing of an appeal are given in The Employment Tribunals (Constitution and Rules of Procedure) Regulations 1993 (SI 1993 No 2687), as amended, for England and Wales and the Employment Tribunals (Constitution and Rules of Procedure) (Scotland) Regulations 1993 (SI 1993 No 2688), as amended, for Scotland.

### PUBLIC REGISTERS OF ENFORCEMENT NOTICES UNDER THE ENVIRONMENT AND SAFETY INFORMATION ACT 1988

1. Under the requirements of the Environment and Safety Information Act 1988, the local authority maintains at its Offices public registers of information on notices which do not impose requirements or conditions solely for the protection of persons at work. These are called “relevant notices” under this Act and will be identified by the inspector serving the notice (see overleaf). Entries will be kept in the public register for a period of at least 3 years.
2. The entry in the register will be made within 14 days either of the expiry of the right of appeal or of the disposal of an appeal. Where a notice is cancelled on appeal no entry will be made. Where an inspector is satisfied that a notice has been complied with, a further entry will be made in the register within 7 days to show this. If a notice is withdrawn or amended the entry on the register will be withdrawn or amended within 7 days.
3. The entry on the register will normally be the front page of the notice form. If you think that the entry for this notice would disclose information about a trade secret or secret manufacturing process, you should give written notice to the local authority **within 14 days**. The local authority will then draft an entry which it believes will not reveal the secret and serve this on you. In the meantime the entry in the register will specify only your name and address, any place involved and the relevant legal provisions.
4. If you are not satisfied with the redrafted entry you have a further right of appeal to the Secretary of State within 14 days. The local authority will give you further information about appeals to the Secretary of State at this time.

### PUBLIC AVAILABILITY OF INFORMATION ON OTHER NOTICES

1. Under the Code of Practice on Access to Government Information the local authority is committed to make available on request information about its actions and decisions, which includes information about the notices it has issued. In general the information that the local authority will make available about a notice is the information on the front page.
2. Information on a notice will not be made available until the right of appeal against the notice has expired or the appeal has been disposed of. Where an inspector is satisfied that a notice has been complied with, this information will be made available at the same time as the information on the front page of the notice.
3. If you think that the information in the notice would disclose commercially confidential information you should give written notification to the local authority **within 14 days**. The local authority will then redraft the information in such a way that it believes will not reveal the commercially confidential information. In the meantime the only information that the local authority would make available would be your name and address, any place involved and the relevant legal provisions.
4. If you are not satisfied with the redrafted information there is no further appeal. However, the local authority will make every effort to agree with you a form of words which would not reveal any commercially confidential information.

**The following does not form part of the Schedule:**

**Important Note: The two documents above are suggested Prohibition Notice templates for guidance purposes only, and local authority officers should consult their own legal department prior to issuing Prohibition Notices.**

## Link URLs in this page

1. The Department of Health website

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsLegislation/PublicationsLegislationArticle/fs/CONTENT_ID=4076283&chk=nEIxNU

2. www.ukstandards.org.uk
   http://www.ukstandards.org.uk/
3. www.habia.org
   http://www.habia.org/
4. www.tpi.org.uk
   http://www.tpi.org.uk/
5. model byelaws
   http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsLegislation/PublicationsLegislationArticle/fs/CONTENT_ID=4076283&chk=nEIxNU
6. Immunisation Against Infectious Disease (The Green Book)
   http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndG CONTENT_ID=4072977&chk=87uz6M
7. http://www.mhra.gov.uk/
8. The Pressure Systems Safety Regulations 2000
   http://www.legislation.gov.uk/uksi/2000/128/contents/made
9. Health Protection Agency
   http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebContentAreaLanding/Page/1153386734379?p=1153386734379
10. www.dh.gov.uk/consultations
    http://www.dh.gov.uk/consultations
11. The Environment Agency [960KB]
    http://publications.environment-agency.gov.uk/pdf/GEHO1105BJVU-e-e.pdf
12. The Environmental Protection Act (1990)
    http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900043_en_1.htm
13. Risks and Health Effects from Tattoos, Body Piercing and Related Practices [95KB]
    http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out230_en.pdf
14. Safe Use of Lasers and Intense Pulse Light Equipment [856KB]
    http://www.habia.org/uploads/Laser_Book_Section_1_&_21.pdf
15. Health and Safety Executive
    http://www.hse.gov.uk/index.htm
16. Department of Health
    http://www.dh.gov.uk/
17. The National Health Service
    http://www.nhs.uk/
18. Health and Beauty Industry Association
    http://www.habia.org/
19. American Academy of Micropigmentation
    http://www.micropigmentation.org/
20. Tattooing and Piercing Industry Union
    http://www.tpi.org.uk/
21. Qualifications and Curriculum Authority
    http://www.qca.org.uk/
22. Blood-borne viruses in the workplace: guidance for employers and employees [103KB]
    http://www.hse.gov.uk/pubns/indg342.pdf

23. HSE online guidance on alternatives to latex gloves
http://www.hse.gov.uk/latex/about.htm
24. Benchtop steam sterilizers - guidance on purchase, operation and maintenance [595KB]
http://www.mhra.gov.uk/home/groups/dts-bi/documents/publication/con007327.pdf
25. guidance on Section 120 and Schedule 6
http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsLegislation/PublicationsLegislationArticle/fs/CONTENT_ID=4076283&chk=nEIxNU
26. Single-use Medical Devices: Implications and consequence of Re-use
http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2024995
27. Norman Noah
http://www.eurosurveillance.org/em/v11n01/1101-221.asp
28. Lactic Acidosis
http://www.emedicine.com/med/topic1253.htm
29. The Pressure Systems Safety Regulations 2000
http://www.legislation.gov.uk/uksi/2000/128/contents/made
30. Tattooing, permanent makeup and piercing in Amsterdam; guidelines, legislation and monitoring
http://www.eurosurveillance.org/em/v11n01/1101-223.asp
31. latex allergy
http://www.hse.gov.uk/latex/