



Tattoo Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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1. Introduction

Based on Resolution (48) 2020, Article No in (4) “The Authority monitors the use of medical devices and products in the Kingdom and takes the necessary and appropriate measures to ensure the safety of their use and maintenance in order to ensure the safety of patients, the public and users of the medical device and product, and the authority shall notify patients or users once it is confirmed that the medical device or product is/are not complying with the of the provisions of this decision.”

In 2019 NHRA issued a **Circular No. (8)** banning the importation and use of tattoo, PMU and microblading ink and machines after the global restriction due to health risks and severe side effects.

This guideline is intended to clarify the reasons of restricting the use of the ink and the device and guide the applicant to get the approval on safe and trusted inks.

2. Definitions

What is meant by the term Tattoo?

A tattoo is a permanent kind of body art. A design is made by penetrating the skin with needles and injecting ink, dyes, and pigments into the deep layer of the skin.

Purposes of using tattoo:

- Cosmetic and decorative body art form.
- Medical therapeutic tattooing was used as a camouflage technique, for breast areola reconstruction after cancer surgery, as camouflage for permanent hair loss after craniofacial surgery, and scars following plastic and reconstructive surgery.



What is meant by the term PMU?

Permanent makeup, as it is most commonly referred to, is a form of cosmetic tattoo that uses needles and artistic tattoo machinery to implant dyes or pigments into the skin with the objective of enhancing facial features — most commonly eyeliners, eyebrows and lips.

PMU is characterized as a semi-permanent application in contrast with the permanent tattoo application

What is meant by the term Microblading?

Microblading is a cosmetic procedure meant to enhance eyebrows using a hand tool with a highly structured blade.

The hand tool allows to make highly accurate superficial scrapes to the brow that follow the direction of the eyebrow hair.

3. Microblading VS Permanent Make Up

There are three main differences between permanent makeup and microblading:

Microblading	PMU
<ul style="list-style-type: none"> • Microblading eyebrows lasts 1 to 2 years. ... Over time, the ink will fade significantly and requires regular touchups. • Microblading is solely for eyebrows. • Done by a tool similar to an exacto knife that does not require batteries or electricity. (manual pen). 	<ul style="list-style-type: none"> • More permanent than microblading and can last up to 3 years, depending on the person. • can be done on the eyes, lips, and brows. • Done by using an electrically powered machine very similar to those regular tattoo artists use



4. Ink Vs Pigments

When tattooing, what is injected into the skin is **ink**, while permanent makeup and microblading uses **pigments**.

Pigments used are iron oxides, usually with some water and glycerine added. Tattoo ink is made up of pigments combined with a carrier and a number of chemicals and heavy metals.

5. Tattoo Ink

Pigments are what give tattoos the often-vivid colors. Some pigments contains heavy metals to make the basic colors. Different ones are used to create specific colors; as follows:

- Mercury for red
- Lead for yellow, green or white
- Cadmium for red, orange or yellow
- Nickel for black
- Zinc for yellow or white
- Chromium for green
- Cobalt for blue
- Aluminum for green or violet
- Titanium for white
- Copper for blue or green
- Iron for brown, red or black
- Barium for white

Some tattoo ink manufacturers will blend heavy metal pigments with lightening agents, like lead or titanium. Pigments can also be made from other elements, including calcium, antimony, beryllium, sulfur or arsenic.

Many of the pigments have been developed for industrial purposes. This includes pigments found in automotive paints or printer ink, which were never intended for use on human skin.



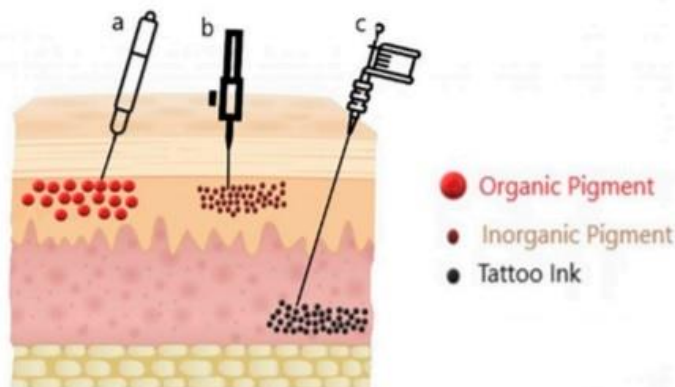
6. Pigments

The most general classification of permanent makeup pigments is into three groups based on the origin of their basic ingredients: iron oxide based, inorganic ones, and organic ones.

Permanent makeup uses **black pigments, different shades of brown, and shades of pink for lip blushing.**

Inorganic Pigment	Organic Pigment
<ul style="list-style-type: none"> The main characteristic of inorganic pigments is the addition of iron oxide elements. As they are synthetically produced from metals they have an inorganic character (clay, ultramarines, titanium oxide, manganese violet). They are used in tattoo and PMU applications with the use of a machine but not with the manual PMU pen (microblading). there are a variety of inorganic pigments based on iron oxides in many colors of tattoo ink and PMU colorants. These colors are yellow, red and black, which are based on heavy metals such as mercury sulfide (red), cadmium sulfide (yellow), chromium oxide (green), or cobalt spinel (blue). 	<ul style="list-style-type: none"> Tattoo colorants contain more than 80% of industrial organic pigments. These kinds of pigments absorb the light resulting in high color strength and have a vivid color in the skin, which lasts for a long time. Organic pigments are affected by sunlight exposure and fade easier, a characteristic, which is the reason why they are more often used in PMU applications.

Tattoo and PMU Colourants



This Figure shows the depth of tattoo and PMU colorants according to organic and inorganic ink and different machine use. Inorganic pigments contain bigger particles of colorants and are placed deeper into the skin. (a) Manual pen (microblading), (b) PMU machine, (c) tattoo machine.

Tattoo and PMU colorants are being injected in the human body to a depth of 1 mm to 3 mm.

Tattoo colorants containing hazardous chemicals have been found on the European market. In samples taken from the tattoo and PMU colorant market, microbiological contamination, heavy metals, polycyclic aromatic hydrocarbons (PAH), primary aromatic amines (PAA), and preservatives were found.

7. Health Risks

Tattoo inks and permanent make-up are a mix of several chemicals. They may contain hazardous substances that cause skin allergies and other more serious health impacts, such as **genetic mutations and cancer Ink pigments have been found in lymph nodes and the liver after migration from the skin area.**

- cause allergic skin reactions, such as an itchy rash at the tattoo site. This can occur even years after you get the tattoo, skin infection is possible after tattooing.
- inflammation called a granuloma can be formed around tattoo ink. Tattooing also can lead to keloids — raised areas caused by an overgrowth of scar tissue.



- If the equipment used to create your tattoo is contaminated with infected blood, you can contract various bloodborne diseases — including methicillin-resistant *Staphylococcus aureus* (MRSA), hepatitis B and hepatitis C.
- tattoos or permanent makeup might cause swelling or burning in the affected areas during magnetic resonance imaging (MRI) exams. In some cases, tattoo pigments can interfere with the quality of the image.

8. Tattoo Removal

Tattoo removal has been performed with various tools since the start of tattooing. While tattoos are generally considered permanent, it is now possible to remove them with treatments, fully or partially.

Tattoo can be removed by 3 techniques:

1. laser removal

Tattoo removal is most commonly performed using lasers that break down the ink particles in the tattoo into smaller particles, **it** is the non-invasive and done by using Q-switched lasers, also this process is the safest but has immediate complications include pain, blisters, crusting and pinpoint haemorrhage...

2. surgical excision

Surgical removal, also called excision tattoo removal, involves cutting off tattooed skin and stitching remaining skin back together. It's the most invasive method of tattoo removal, but also the only guaranteed way to completely remove a tattoo. but it will always leave a scar. As a result, it's usually only done on smaller tattoos.

3. Dermabrasion

Dermabrasion involves using a sanding device to remove layers of skin to allow ink to leach out. Its effectiveness varies widely from person to person, making it a less popular option.

It is not recommended for very sensitive skin or a skin condition like eczema and may also have a higher risk of experiencing bleeding, bruising, and changes in your skin color following the procedure. People with darker skin may also have a greater risk of skin pigment changes.



9. Ink Market and Regulation

Tattoo and PMU artists use tattoo colorant suspensions from different commercial suppliers in this field. Until recently there was no limitation on the use of certain chemicals in tattoo inks and in permanent makeup colorants.

To protect users, substances and hazardous chemicals found in **tattoo inks and PMU are regulated in the EU under:**

➤ **REACH.**

(the Registration, Evaluation, Authorization and Restriction of Chemicals regulation)

The REACH Regulation sets out procedures for collecting and evaluating information on the properties and hazards of substances.

➤ **ECHA (The European Chemical Agency)**

It is an EU agency that implements legislation on chemicals to protect health and the environment. In other words, it bans chemical substances or, in cases of increased risk, calls on industry to develop safer alternatives.

European companies or companies that place their products on the market in Europe must register the substances they use. While ECHA evaluates individual registrations for compliance with REACH requirements. While individual EU member states also re-evaluate selected substances themselves to address initial concerns for human health or the environment.

➤ **The European Council Resolution ResAP (2008)1**

In 2008, it was created regarding the requirements and criteria for the safety of tattoos and permanent makeup guides for the manufacturers of tattoo inks. Currently, Netherlands, Norway, France, Germany, Spain, Switzerland and Sweden have adopted national regulations on tattoo ink manufacturing and Austria, Italy, Denmark and Slovenia are using the resolution to control tattoo inks.



10. Classification

As many manufacturers are planning to comply with new regulations to guarantee the safety of the final products , NHRA is opening the chance to evaluate the pigments by submitting classification form.

Once the ink is approved, the devices approval is done by submitting **Saloon Form** with the required documents for evaluation. (*please refer to Cosmetic Devices used in Saloons Guideline*)

Classification Results:

- The device is not claimed to be used for micro needling or other medical practice and approved to be used in saloon.
- The device is used for medical purposes and must be used by a licensed healthcare professional in a licensed healthcare facility.

[List or photo of inks found in Bahrain link](#)

11. Ink Classification Requirements

Main Requirements:

- Ink Form
- A Free Sale Certificate (FSC) from the country of origin of the products, issued by the health regulatory authority of that country (e.g. NHRA).
- Ink ingredient list and it should highlight the pigment/colorant international ID/code for each issued by the manufacturer.
- Ink international code must be listed under the approved colorant list issued by the ECHA/EU with evidence that the colorant is in the approved list.
- Lab report confirming the ingredient list issued by an internationally recognized lab.
- Label of the ink.
- Lab report confirming compliance with the most recent ResAP resolution.

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Labelling Requirements

- Name and address of the manufacturer or the person responsible for placing the product on the market.
- Minimum date of durability.
- Conditions of use and warnings.
- Batch number used by the manufacturer for batch identification.
- List of ingredients according to their International Union of Pure and Applied Chemistry (IUPAC) name, CAS number (Chemical Abstract Service of the American Chemical Society) or Color Index (CI) number.
- Guarantee of sterility of the contents.

12. References

(1) ResAP (2008)1

https://search.coe.int/cm/Pages/result_details.aspx?ObjectID=09000016805d3dc4

(2) List of Prohibited Substances in Cosmetics

https://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20II_v2.pdf

(3) List of Colorants allowed in Cosmetic Products.

https://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20IV_v2.pdf

(4) Safety of tattoos and permanent make-up (European Commission, JRC Technical Reports)

<https://publications.jrc.ec.europa.eu/repository/handle/JRC96808>

(5) FDA

<https://www.fda.gov/cosmetics/cosmetic-products/tattoos-permanent-makeup-fact-sheet>



(6) ECHA

<https://echa.europa.eu/hot-topics/tattoo-inks#:~:text=The%20top%20layer%20of%20skin,designs%20that%20resemble%20make%20Dup.>

(7) Classification Form for Devices used in Saloons

<https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/salon%20foorm%20final%20DEC%202021.pdf>

(8) Safety of Tattoos and Permanent Make up (PMU) Colorants Article.

<https://www.mdpi.com/2079-9284/8/2/47/pdf#:~:text=It%20is%20commonly%20known%20that,being%20placed%20in%20the%20body.>

(9) Tattoo Removal Article

<https://www.healthline.com/health/tattoo-removal-how>