# DEVICE: KIPIC HYPODERMIC NEEDLES FOR SINGLE USE

| **1. ADMINISTRATIVE INFORMATION ON THE COMPANY** | | |
|---|---|---|
| 1.1 | **Name:** Aesthetic Group | |
| 1.2 | **Adress:**<br>Z.A. La Gobette<br>60540 Puiseux-Le-Hauberger<br>France | Phone: +33 03 44 74 19 95<br>Fax: +33 03 44 74 18 94<br>E-mail: info@aestheticgroup.fr<br>Website: www.aestheticgroup.fr |
| 1.3 | **Vigilance and PRRC contact details:**<br>Valérie Boquet | Phone: +33 03 44 74 19 95<br>Fax: +33 03 44 74 18 94<br>E-mail: info@aestheticgroup.fr |

## 2. INFORMATIONS ABOUT THE DEVICE OR EQUIPMENT

**2.1 Name:** Hypodermic needles for single use

**2.2 Tradename:** Kipic™

**2.3 Nomenclature code:**
UMNDS: 12-745
GMDN: 59230
HS Code: 90183210

**2.4 LPPR code (if applicable):** N/A

**2.5 Class of the device:**
Disposable Needles (Hypodermic Needles) is an invasive device intended for transient use. According to rule 6 of Annex VIII of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, Disposable Needles (Hypodermic Needles) belongs to class Ⅱa medical device.

**Number of the notified body:** 0123

**Date of first entry on the market in the EU:** N/A

**MD Manufacturer:** Zhejiang kindly medical devices Co., Ltd.
Add: No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District, 325025 Wenzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

**SRN:** CN-MF-000007594

**BASIC UDI :** 69230334202002a00401LY

**2.6 Description of the device:**
The Kipic ™ disposable sterile needles are designed for hypodermic injections especially for infusion of drugs and blood collection, treat fat deposits and cellulite, alopecia, skin rejuvenation, pain management, osteoarthritis ....
They are available in different lengths and diameters. The needles consist of a straight cannula with bevel and a Luer Lock base.

**Procedure pack:** No ~~Yes~~

**2.7 Catalogue references:**

| Item code | Color code | External diameter (mm) | Diameter (Gauge) | Length (mm) |
|---|---|---|---|---|
| KIPIC21G80 | Green | 0,82 | 21 | 80 |
| KIPIC25G42 | Orange | 0,50 | 25 | 42 |
| KIPIC27G04 | Grey | 0,40 | 27 | 4 |
| KIPIC27G13 | Grey | 0,40 | 27 | 13 |
| KIPIC27G42 | Grey | 0,40 | 27 | 42 |
| KIPIC30G04 | Yellow | 0,30 | 30 | 4 |
| KIPIC30G13 | Yellow | 0,30 | 30 | 13 |
| KIPIC30G25 | Yellow | 0,30 | 30 | 25 |
| KIPIC32G04 | Green | 0,23 | 32 | 4 |
| KIPIC32G08 | Green | 0,23 | 32 | 8 |
| KIPIC32G13 | Green | 0,23 | 32 | 13 |
| KIPIC33G04 | Black | 0,20 | 33 | 4 |
| KIPIC33G08 | Black | 0,20 | 33 | 8 |
| KIPIC33G13 | Black | 0,20 | 33 | 13 |
| KIPIC34G04 | Orange | 0,18 | 34 | 8 |

**Packaging :**
UCD (Control Unit): Blister of 1 piece
CDT (Multiple of the UCD): Boxes of 100 pieces

All the needles are equipped with a polypropylene transparent sterility protection tube. This tube protects the bevel of the needle so that it is not blunt and is suitable for ethylene oxide sterilization.
The needles are packaged in an individual medical grade bag, which guarantees the protection of the needle and the maintenance of the sterile condition.

**Labelling:** other document

**2.8 Composition of the device and accessories:**

| **COMPONENTS** | **MATERIALS** | **TYPE OF CONTACT** |
|---|---|---|
| Needle tube | Medical grade 304 stainless steel | Direct |
| Protective cap | Polypropylene | Indirect |
| Needle hub | Polypropylene | Direct |

| | | |
|---|---|---|
| Latex: | ~~Presence~~ | Absence |
| Phthalates (DHP): | ~~Presence~~ | Absence |
| Product of animal or biological origin: | ~~Presence~~ | Absence |
| Bisphenol A | ~~Presence~~ | Absence |

**Associated devices and accessories:** According to needle variants, Disposable Needles (hypodermic needles) should be used with syringe. Requirements for Disposable Needles (hypodermic needles) have been specified in ISO 7864.

## 3. STERILIZATION PROCESS

**MD sterile:** YES ~~NO~~

**Sterilization method of the device:** Ethylene Oxide
**Shelf life:** 5 years

## 4. PRESERVATION AND STORAGE

Store in a dry environment and keep away from sunlight.

## 5. SAFETY OF USE

### 5.1 Technical safety:

The MRI compatibility of our needles has not been tested
Needle is X-ray detectable
Like all stainless steel needles, steel could be altered by hydrochloric acid

### 5.2 Biological safety:

Be careful to follow the usual aseptic procedures
After use, handle and dispose of with other contaminated devices

## 6. INSTRUCTIONS FOR USE

### 6.1 Instructions for use:

1. Select appropriate matching device with standard luer and gauge as per actual requirement.
2. Check package integrity before use.
3. Check the integrity of the package before use; if the primary package is opened or damaged or in case there is foreign matters such as hair, insects, do not use the product.
4. Open the package and take out the product from the package. Take care to prevent the product falling to the ground.
5. Inspect product, do not use the product in case of abnormal product conditions including protective cap detachment, inverted or unbonded needle tube.
6. Assembled it with the standard luer of disposable syringe.
7. Perform hypodermic injection on the human body according to clinical nursing science operating method.
8. Dispose the product after use in conformity with the instituion's regulatory for contaminated sharps and according to valid national regulations for such products. Take care to avoid accidental needle stick injury during sharp disposal.

### 6.2 Intended purpose:

Disposable Needles (Hypodermic Needles) is intended to inject or withdraw fluids from primarily the human body. The product is intended to be used with disposable syringe, the needle shall be used immediately after medication filling.

### 6.3 Intended users:

Healthcare professionals

### 6.4 Intended patient population:

Not limited, mainly pediatrics and adults

### 6.5 Indications:

Patients who needle hypodermic injection therapy

### 6.6 Using precaution and warnings:

- The product must not be reused.
- Do not resterilize
- Entrust the operation and use of the product and accessories only to persons with the required training, knowledge or experience.
- Physicians administering drug therapy should be aware of the chemicals / medications injected, dosages, particular side effects and potential interactions.
- Use the product only for the intended purpose, see Scope of application / see Contraindications.
- Before each use, make a visual examination of the product: absence of loose, bent, broken, cracked, worn and broken parts.
- Never use a damaged or defective product. Dispose of any damaged product immediately.
- Check the integrity of the primary packaging before use. Never use this device when the primary packaging is damaged.
- Do not use beyond the expiry date
- Be very careful to apply the usual aseptic procedures due to the risk of infection
- Do not exert excessive force that may cause the needle to break
- Solutions based on hydrochloric acid can alter the steel
- Check the integrity of the needle during removal
- For single use only. Discard after use
- After use, handle and dispose of contaminated devices - Do not recap
- Use immediately after opening the packaging and avoid polluting

### 6.7 Contra-indications:

N/A

## 7. ADDITIONAL PRODUCT INFORMATION

**Biocompatibility**

Comply with the requirements of the standard for biocompatibility of medical devices.

## 8. ANNEXES

- EC Certificate
- EU Declaration of conformity
- IFU
- Warnings

## 9. PICTURES