

### FILLERS BDDE FREE

### MADE IN FRANCE

#### Gino CHITARRINI

President of CM AESTHETIC



#### A pioneer in the field of plastic surgery.

Gino CHITARRINI has spent his entire professional career in the medical field (over 50 years) more precisely in plastic surgery where he created several breast implant manufacturing companies in France, notably SILICONE MÉDICALE in 1975, then its Brazilian subsidiary SILICONE MEDICAL DO BRAZIL (SILIMED) with the help of Dr Ivo PITANGY, then LABORATOIRES SEBBIN in 1980.

To respond to the evolution of the anti-aging market, he bought in 2013 the laboratory CM AESTHETIC Ltd and moved to Puiseux-le-Hauberger. He presented the very first range of hyaluronic acid fillers without BDDE, a real innovation attracting doctors and distributors from all around the world.

Guarantying a 100% absorbable product, G. CHITARRINI invents the very first range of MEDIFEEL® fillers based on natural components. The range is subject to European rules (CE marking) for the design, manufacture and output control of implantable and sterile hyaluronic acid medical devices, and is regularly checked by the notified body. This is why CM AESTHETIC Ltd, offers a Made in France: all its raw materials are manufactured in France.

In 2017, CM AESTHETIC Ltd, entrusts MEDISKIN France sas (directed by Adnan BEN JEMIA, collaborator and ral partner of Gino CHITARRINI for more than 20 years) for the marketing of the MEDIFEEL® range.



# MEDIFIEL®

### The BDDE free Filler

MediFeel® is a range of injectable skin implants with hyaluronic acid without BDDE, natural and completely free of toxic chemical components. Biocompatible, completely absorbable and not harmful to health, thanks to the perfect combination of hyaluronicacid and CarboxyMethyl Cellulose, a natural gelling agent. This quality makes MediFeel Fillers one of the healthiest products used by dermatologists and in aesthetic medicine.

In the form of an intradermal, monophasic, viscoelastic, sterile, colorless, transparent structuring gel; it does not contain pyrogens and has a high molecular weight. MediFeel® does not contain any elements of human or animal origin.

MediFeel® complies with all European rules and standards relating to implantable medical devices: 🕻 🕬

#### **HYALURONIC ACID**

The hyaluronic acid used in MediFeel Fillers is composed of sodium hyaluronate developed by a bacterial fermentation process, using non-genetically modified Streptococcus equistrains, of high molecular weight and without animal proteins, made in France.



#### CARBOXYMETHYL CELLULOSE

MediFeel® is BDDE FREE (ButanediolDiglycidyl Ether; whose recent studies prove its toxicity), PEG FREE and without Divinyl sulfone. It is stabilized by CarboxyMethyl Cellulose, a natural gelling agent (also used in the food industry) which has the same action as a crosslinker without any toxicity.



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 $R = H \text{ or } CH_2CO_2H$ 

Thanks to this perfect combination: we can affirm that MediFeel do not present any carcinogenic risk. Studies carried out by practitioners on 100 patients have shown that the use of our products does not cause any serious side effects, for a duration lasting from 4 to 6 months, with a natural effect without bruising.

## MEDIFEEL® 12mg MESOFILLER

#### **PURE HYDRATING HYALURONIC ACID**

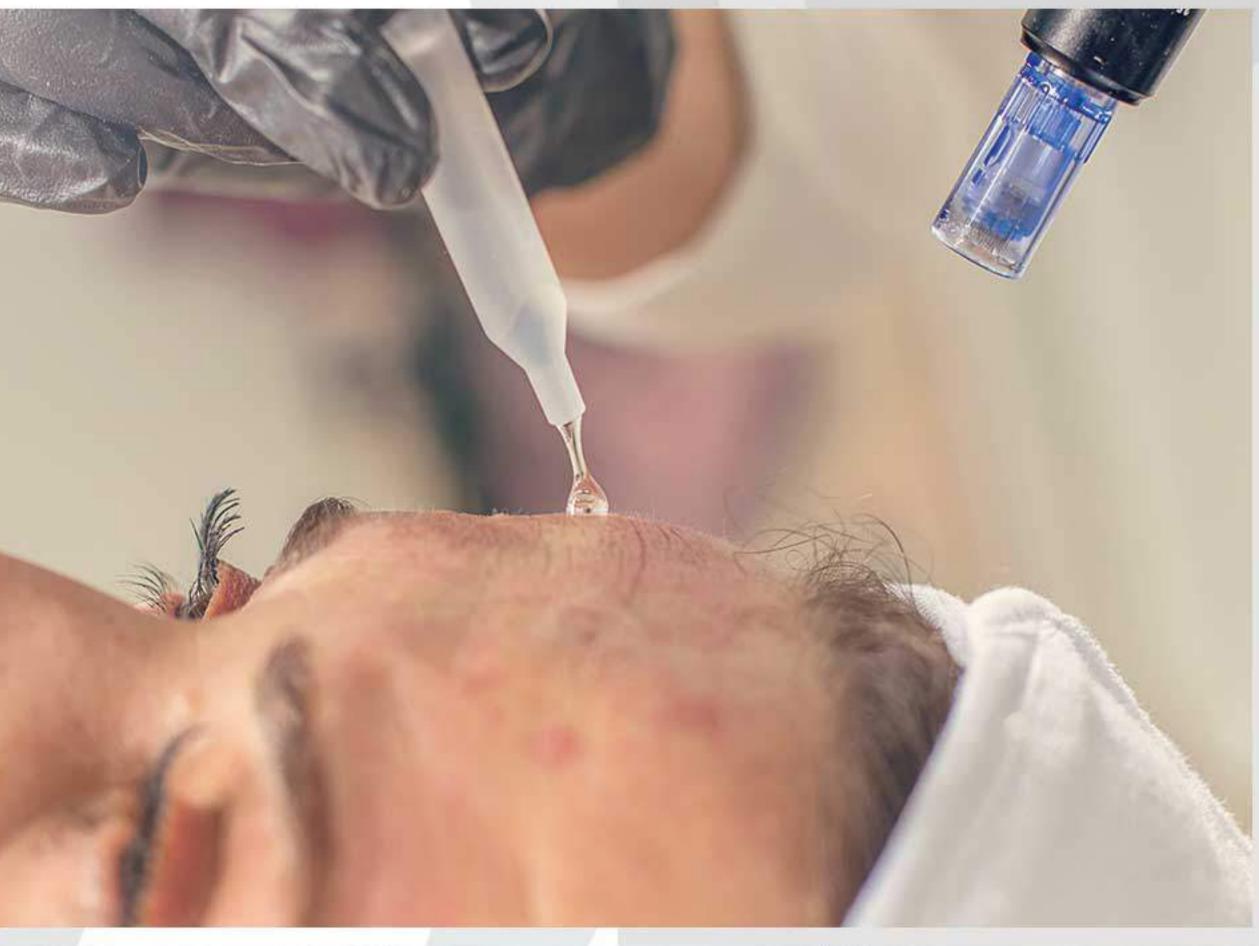
MEDIFEEL® 12 is a powerful, innovative anti-aging Mesotherapy treatment with an impressive result. It fades wrinkles, unifies the skin tone, brightens it, hydrates the skin allowing it to breathe better. It has the power to regulate it and give it a smooth «lift effect». This is the guarantee of the «Youth Capital» of a firm face regaining its elasticity in depth. Adapting to the uniqueness of each woman and each man, for all skin types.

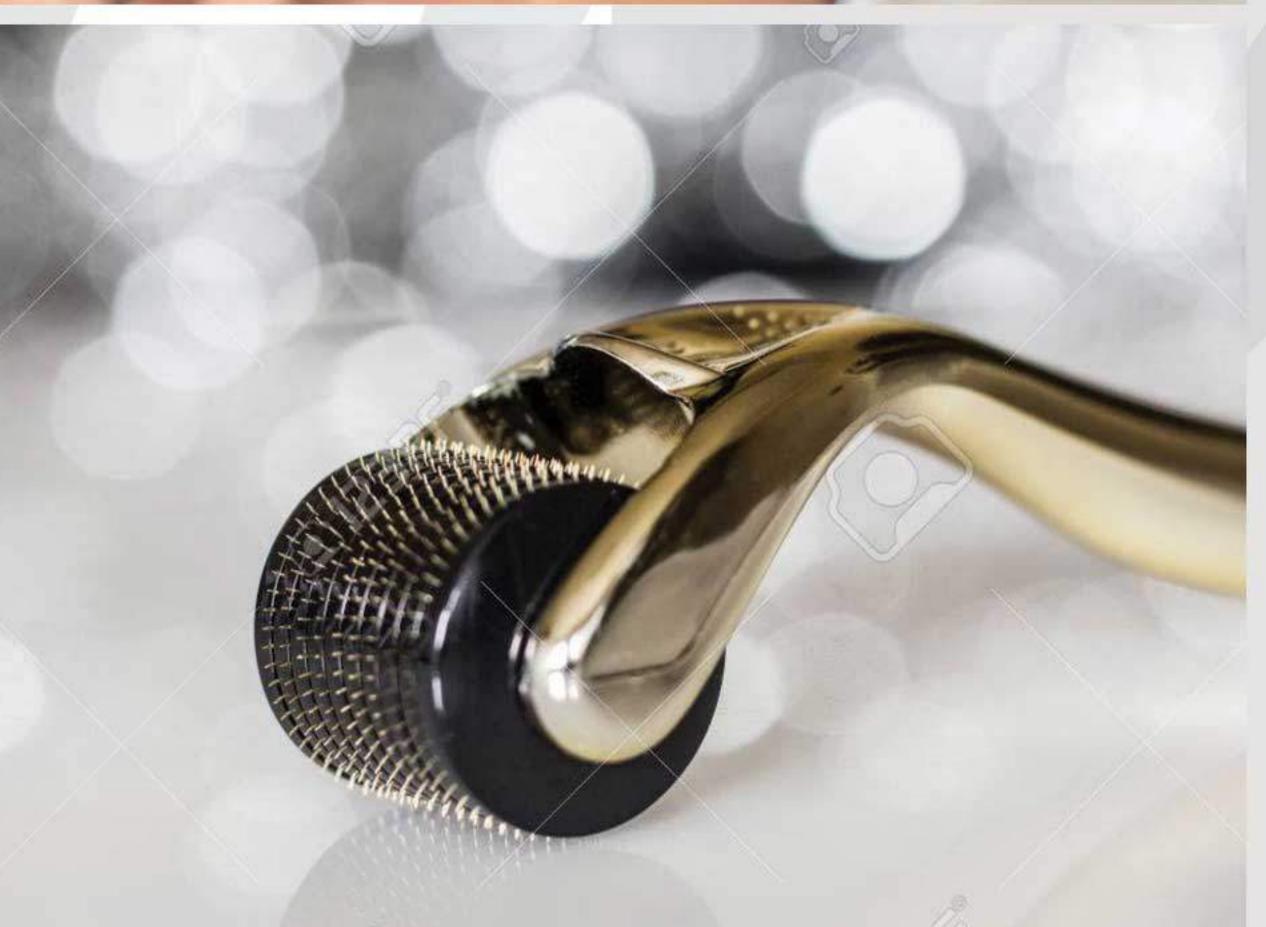
Its hyaluronic acid content helps maintain and strengthen the production of collagen to intensely hydrate, wake up the skin and visibly reduce wrinkles.

MEDIFEEL® 12 can be used in injectable mesotherapy as well as topical mesotherapy on the face, neck and décolleté. It is also very popular with beauty centers, which use it with all kinds of tools and non-invasive penetration technology.









#### COMPOSITION

- Hyaluronic Acid 12mg/ml
- Water for injection
- Tampon Phosphate Ph 7,2.

#### **METHODS OF USE**

- Injection needles or cannulas
- Mesotherapy needles.
- Meso Roller
- All machines or technologies for the pene tration of active agents.

#### **BOXES CONTENT**

- A pre-filled syringe of 2ml or 4 vials filled with 5ml of sterile gel injectable implant.
- Instructions for use
- Traceability labels
- Traceability card

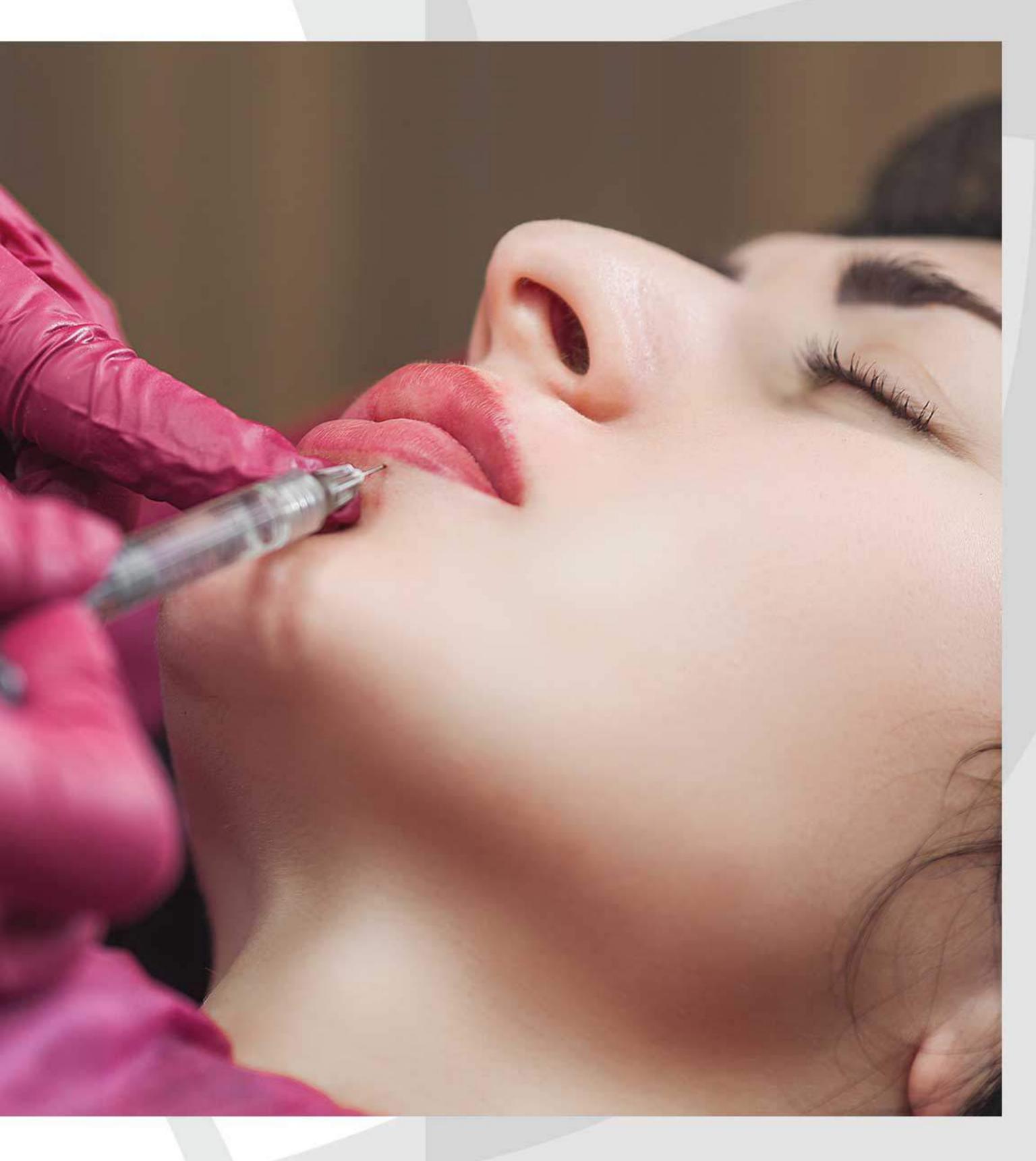


## MEDIFEEL® 20mg VOLUME I

MEDIFEEL® 20mg is an injectable implant indicated for the filling of fine lines. Recommended for the treatment of wrinkles around the lips, inter-eyebrow wrinkles, forehead wrinkles and periorbital wrinkles.

Also indicated for increasing the volume of the lips, by injection into the lining of the lips.





#### COMPOSITION

- Hyaluronic Acid 20mg/ml
- Water for injection
- Tampon Phosphate Ph 7,2.
- CMC (Carboxy Methyl Cellulose)

#### **TECHNIQUES OF INJECTIONS**

- Injection needles or cannulas

#### **BOXES CONTENT**

- Syringe pre-filled with 1 ml sterile gel injectable implant
- Instructions for use
- Traceability labels
- Traceability card



## MEDIFEEL® 25mg VOLUME II

MEDIFEEL® 25mg is an injectable implant indicated for the treatment of medium and deep wrinkles, nasolabial folds and lip augmentation. It corrects the loss of volume and shapes the contours of the face. It is also recommended for the augmentation of the cheeks, cheekbones and the oval of the face.

This product is particularly versatile and can be used to treat all areas of the face!





#### COMPOSITION

- Hyaluronic Acid 25mg/ml
- Water for injection
- Tampon Phosphate Ph 7,2.
- CMC (Carboxy Methyl Cellulose)

#### **TECHNIQUES OF INJECTIONS**

- Injection needles or cannulas

#### **CAPACITY OF THE BOXES**

- Syringe pre-filled with 1 ml sterile gel injectable implant
- Instructions for use
- Traceability labels
- Traceability card



## MEDIFEEL® 28mg VOLUME III

**MEDIFEEL® 28mg** has a volume effect thanks to the size of the particles which compose it. It is designed to give or restore volume and redraw the contour of the face. It fills the deepest furrows and folds of the face, such as the nasolabial folds or severe folds. It can also increase the volume of the cheeks, cheekbones and the oval of the face.

MEDIFEEL® 28mg helps to erase or to correct the deepest aging signs. It gives the skin a firmer appearance thanks to the hyaluronic acid present in large quantities which improves the elasticity of the skin and its hydration.

It's the only Filler of 28mg on the market!





#### COMPOSITION

- Hyaluronic Acid 28mg/ml
- Water for injection
- Tampon Phosphate Ph 7,2.
- CMC (Carboxy Methyl Cellulose)

#### **TECHNIQUES OF INJECTIONS**

- Injection needles or cannulas

#### **CAPACITY OF THE BOXES**

- Syringe pre-filled with 1 ml sterile gel injectable implant
- Instructions for use
- Traceability labels
- Traceability card

### Injection Recommondations

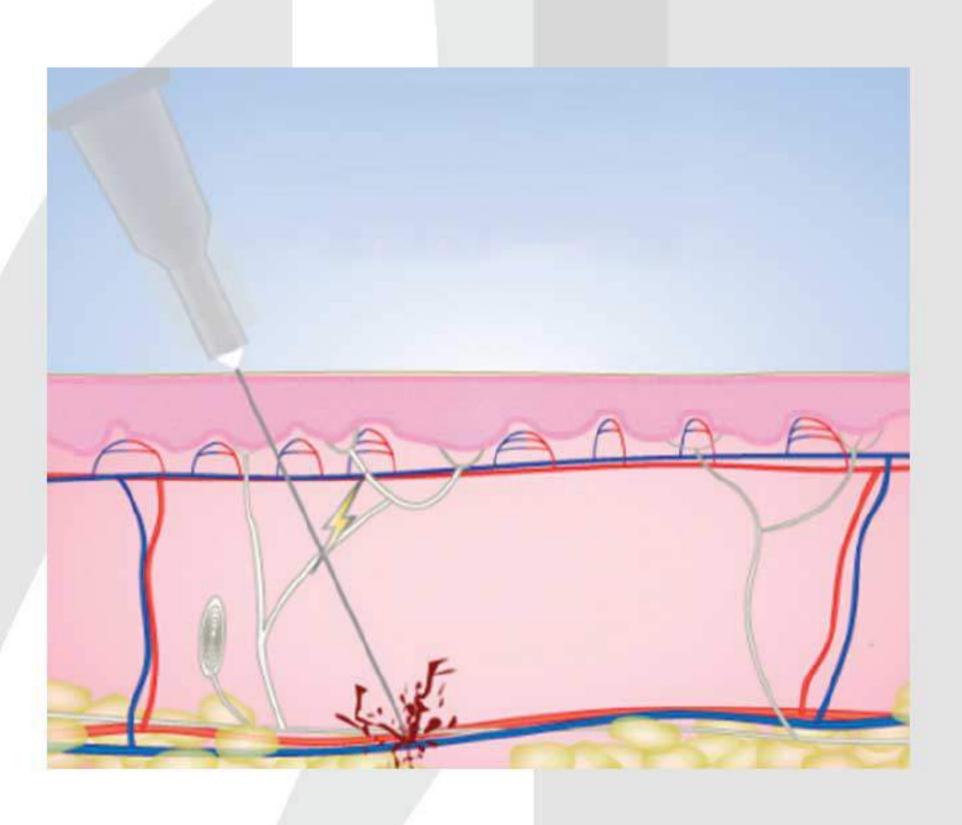
**MediFeel**® is a dermal filler based on a hyaluronic acid free of chemical agents; it does not contain any BDDE the toxic and irritating crosslinking agent which modify the hyaluronic acid natural aspect.

**MediFeel**® is jellified by a natural way with CMC **(Carboxy Methyl Cellulose)** a natural, vegetal origin jellifying agent which ensures the product stability and don't provoke any side effects comparing to the other marketed products crosslinked with BDDE or any other chemical cross linker.

The injections recommendations below must be strictly followed to ensure the sustainability of the treatment :

- 1. Adapt the product viscosity to the treated area to have an efficacy and natural result.
- 2. Make rigorous and wide skin disinfection.
- 3. Inject MediFeel® in an atraumatic way as follow:
  - Favor the micro cannulas by making a pre-dermal penetration hole away from vascular risk areas and from nerves (usually 25 or 27G).
  - Insert gently the cannula by tunneling the area to be treated and then inject with a slow and gentle way "Liner threading method".
  - If the patient feels pain, stop the treatment and restart once the pain has disappeared.
  - For the areas treated with needles, make the least possible bevel injection holes facing the skin surface by always injecting slowly.
  - Avoid the most you can the ecchymosis which contribute to the fast hyaluronic acid resorption.
  - Suspend momentarily any anticoagulant treatment before injection (if possible), make an ARNICA type prevention if necessary.
- 4. Do not inject in an inflammatory, infected or with active skin lesions area.
- **5.** At the end of the injection perform a gentle massage of the entire treated area to spread harmoniously **MediFeel**®.

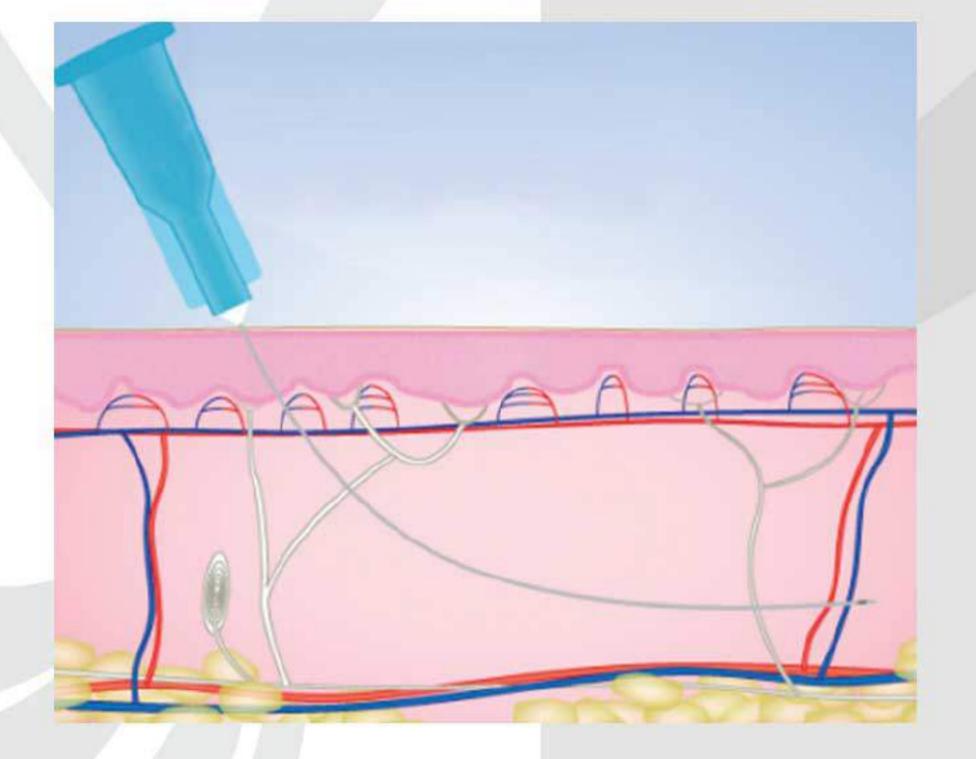
Any traumatic and non-compliant injection will contribute to resorb fastly the hyaluronic acid.



#### Injection with Hypodermic Needle

The injection with a sharp needle can traumatize blood vessels; causing ecchymosis which can long last and create inflammation in the treated area.

Hyaluronic acid injected by needle can exceptionally create a vascular embolus which may cause a necrosis area.



#### Injection with Micro-Cannula

An injection with micro-cannula is the most adapted one, by introducing it in the dermis and by its mossy tail end; we can safely get around blood vessels and nerve ramifications without creating a trauma.



#### ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
ЗЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

## EC DESIGN-EXAMINATION CERTIFICATE

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll. (Annex II of Directive 93/42/EEC)

No.: MED 190030

The Electrotechnical Testing Institute, Notified Body No. 1014, performed the design examination of medical device

Sterile implantable medical device with hyaluronic acid MediFeel 12, MediFeel 20, MediFeel 25, MediFeel 28 class III

in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II clause 4 of Directive 93/42/EEC) at

manufacturer

CM AESTHETIC LIMITED
UNIT 4, STRATA HOUSE 34A WATERLOO ROAD, LONDON NW2 7UH, United Kingdom

and states that the design of medical device meets the provisions of Government Order No. 54/2015 Coll. (Directive 93/42/EEC)

The details of the medical device design examination are presented in the audit report No. MED000052-01/01 of: 14.08.2019.

The manufacturer must inform the notified body about any intention of substantial changes to the approved design of medical device which could affect the conformity with essential requirements in accordance with Annex 1 of Government Order No. 54/2015 Coll. (Annex I of Directive 93/42/EEC). In that case the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

Edition 1

The first issue of this certificate from 16.08.2019 with validity until 26.05.2024

The validity of this Certificate is limited until: 26.05.2024

16.08.2019

Prague

Made

Mgr. Miroslav Sedláček Head of Certification Body





#### ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE ЗЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

### EC CERTIFICATE FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll. (Annex II of Directive 93/42/EEC)

No.: MED 190029

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer

CM AESTHETIC LIMITED

UNIT 4, STRATA HOUSE 34A WATERLOO ROAD, LONDON NW2 7UH, United Kingdom

for design, manufacturing and final inspection of medical device(s)

Sterile implantable medical device with hyaluronic acid MediFeel 12, MediFeel 20, MediFeel 25, MediFeel 28 class III

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. MED000052-01/01 of: 14.08.2019.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 16.08.2019 with validity until 26.05.2024 The validity of this Certificate is limited until: 26.05.2024

16.08.2019

Prague

Mgr. Miroslav Sedláček Head of Certification Body



Stamp





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