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Be Filler Intradermic

THECNICAL DATA SHEET

MEDICAL DEVICE class III (Directive 93/42/ECC and sub sequent amendments/additions) CE 2195

Revisione n°	03
Data	10/01/2022

1. DEVICE CLASSIFICATION

MEDICAL DEVICE CLASS III (Directive 93/42/ECC and subsequent amendments/additions).
CE Mark 2195

2. PRODUCT NAME

- Be Filler INTRADERMIC FINE
- Be Filler INTRADERMIC MEDIUM
- Be Filler NTRADERMIC PLUS

3. DESCRIPTION

- Be Filler INTRADERMIC is a sterile, transparent gel of stabilized hyaluronic acid of non-animal origin. Be Filler INTRADERMIC is supplied in a glass syringe with a Luer-Lock fitting.
- The contents of the syringe have been sterilized using moist heat (121°C, 30 min., 0,1MPa).
- Disposable sterile needles are provided with syringe.
- Be Filler INTRADERMIC is based on an innovative technology “Esteri Fyl Technology” that guarantees an absolute purity after the cross-linking, improving the density and elasticity of cross-linked hyaluronic acid , which remain void of free residues.
- Be Filler INTRADERMIC is highly tolerated because it is purified and free of endotoxins and other toxic substances. Furthermore, thanks to the cross-linking and purification process, BDDE levels (chemical agent used for the cross-linking process) are at the limit of analytical determination.

4. THECNICAL DATA

	Be Filler INTRADERMIC FINE	Be Filler INTRADERMIC MEDIUM	Be Filler INTRADERMIC PLUS
Treatment indications	Small lines of expression	- Fairly deep wrinkles - Lip countour - Lip volume	- Deep wrinkles - Increase of Lip volume - Increase of cheek volume - Face contourning
Aspect	Transparent, pure gel	Transparent, pure gel	Transparent, pure gel
Content	Cross-linked hyaluronic acid	Cross-linked hyaluronic acid	Cross-linked hyaluronic acid
Concentration	20 mg/ml	20 mg/ml	20 mg/ml
pH	7 (neutral)	7 (neutral)	7 (neutral)

Residues from cross-linking	None	None	None
Particle size	200µ	400µ	600µ
Volume of the syringe	1 ml	1 ml	1 ml
Needle type	Ago a parete sottile	Ago a parete sottile	Ago a parete sottile
Needle size	27G ½"	27G ½"	27G ½"
Handle and grip	Ergonomics	Ergonomics	Ergonomics
Storage conditions	2-25°C	2-25°C	2-25°C

- Each treatment unit is identified by a serial number to guarantee maximal traceability and safety of the product.

5. COMPOSITION

Hyaluronic acid 2%, sodium chloride, sodium phospate dibasic, sodium phosphate monobasic, 1,4-Butanediol diglycidyl ether, water.

6. INTENDED USE

Be Filler INTRADERMIC is intended to be used for soft tissue augmentation and restoration of facial lipoatrophy in patients over the age of 21 years.

7. WARNINGS

- The box contains complete instructions for use and handling.
- The product is for single use only.
- Only qualified medical professionals must administer the treatment.
- Any injections include the risk of infection. Keeping an aseptic environment and standard procedures help prevent cross-infection.
- Extreme precaution is needed when operating near weak tissues such as nerves and veins, or any permanent implants.
- Do not use if product is expired or if package is opened or damaged.
- The patient must be informed of the purpose, expected results, precautions, and possible adverse events before treatment.
- Proper injection technique is essential to obtain favorable results.

8. AUTHORIZATION AND CERTIFICATION

Certifacte CE Notify Body N° 2195 – SZUTEST

Medical Device class	CND classification
III	P900402

INFORMATION RESERVED FOR SANITARY OPERATORS AND PROFESSIONAL USERS

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