INFORMED CONSENT

The regeneration system for dermal biogenesis is a non-invasive medical treatment, consisting in injecting, through a fine needle or a cannula. The procedure is relatively painless and a topical anaesthetic can be applied prior to treatment with Sunekos.

The treatment normally lasts about 15-20 minutes and at the end you can immediately resume normal activities.

The intradermal plant of natural chemically unmodified high and low molecular weight hyaluronic acid, plus amino acids of collagen and elastin (in Sunekos 200 and 1200) is one of the methods used for rejuvenation Hyaluronic acid and the amino acids of collagen and elastin are substances already present in the human body, they are reabsorbed and are used for the synthesis of a new dermal matrix. The duration of the effect depends on multiple factors (individual characteristics, sun exposure, skin treatments, etc.). The Practitioner is the only competent person to judge if the implant can be performed.

Noticeable improvements after Sunekos treatment are the following:
- increased firmness and elasticity of the skin
- brightness and turgor
- improvement of fine lines and decrease of thin wrinkles

The regeneration system for dermal biogenesis is a treatment indicated both for young, still elastic and vital skin, to slow down the physiological aging process, and for mature skin to reduce the signs of aging, reactivating cellular functionality.

Sunekos 200 or 1200 have not had any reportable allergic reactions reported to date so its use does not require preliminary tests. However, we advise that if you were to have a reaction, you would need to inform your practitioner.

The treatment is carried out as follows:
- after disinfecting the area to be treated, the Health Care Professional (HCP) inserts the needle or microcannula along the line or wrinkle, then withdraws it gradually, releasing the product at the same time;
- after the product has been injected the HCP may perform a gentle massage to shape the treated area.

I declare that I am aware of the following:
- that there is a possibility, at least in theory, that the components of the injected material may cause an allergy;
- that the percentage improvement of the defect to be corrected, the extent and duration of the result cannot be accurately predicted in advance;
- that it is not possible to establish the number of sessions required by any given patient. Three - four sessions are usually required in close succession (generally two weeks apart) to achieve effective filling;
- the intradermal implantation of biomaterials, such as hyaluronic acid, is considered a safe medical-surgical procedure; however, in some cases, as occurs in all medical procedures, the body may respond and react in way that is not always entirely predictable, such as, for example, the formation of bruises, hematomas, herpes or bacterial infections, oedemas, nodules, cysts and inflammation. These reactions can occur even if the medical-surgical procedure is carried out with skill, prudence and diligence;
- any complication and/or defect can be treated and/or corrected. To this end, I consent in advance, to undergo treatments of the case by the same HCP who treated me, without involving an additional payment. I reserve the right to refer to another HCP and, in this case, I hereby waive any claim against HCP …….. or any demand for compensation or indemnity for expenses incurred under the new doctor who treated me;
- I accept that non-invasive assessments (painless and harmless) and/or photographic recordings shall be carried out on myself before, during and after treatment. This documentation will only be used by the Practitioner for the purpose of clinical documentation or as evidential documentation in the event of dispute with the patient.

I also declare:
- that I am in good health;
- that I have never suffered from allergies to injectable components
- that I do not suffer from moderate or severe allergic syndromes
- that I have informed HCP…….. of any previous intradermal implants (type, date, outcome)
- that I have never undergone the interdermal implantation of permanent substances (silicone, gore-tex, polyacrylamide, etc.)
- that I do not suffer from autoimmune diseases
- that I am not currently pregnant or breastfeeding
- that I do not take anti-cancer, immunomodulatory or interferon drugs
- that I do not take anticoagulants or antiplatelet agents(e.g. aspirin).

The medical information I have provided is correct to the best of my knowledge. I understand that the photographs and information I have provided will be stored and secured as part of your patient records in accordance with the data protection act.

I understand that the aim of Sunekos injections is for improvement not perfection, there isno guarantee of results and it should not be considered as a "cure" for the condition being treated.
I have had sufficient opportunity to discuss the procedure and ask questions.
I understand the failure to provide accurate information may compromise the safety and effectiveness of any treatment or advise that I may receive.
I accept and understand that the goal of this treatment is improvement, not perfection and that there is no guarantee that the results will be achieved.

I, the undersigned,

Surname_____Name_____

Authorise HCP_____

To carry out the intradermal implant of:

PRODUCT NAME: _____BATCH NO.: _____

Signed in ……., on …….. (two copies, one of which is in my possession)

Read, understood and accepted

Patient's signature HCP's signature