Informed consent

CLINICAL AND INSTRUMENTAL EVALUATION OF BIO-REVITALIZING EFFECT ON FACE WITH FOLIAGE HYDROFIL MEDICAL DEVICE

N° subjest : _____

Center: **Poliambulatorio di Medicina Estetica della Casa della Salute, Largo XII Ottobre 62**

City: **Genova**

Principal Investigator: **Dott.ssa Tiziana Lazzari**

Phone number: **+ 39 010 8078631**

(this statement must be signed and dated personally by the individual, or the legal representative or independent witness and the person who conducted the discussion regarding informed consent)

I the undersigned _____ born in _____ on___/____/____,

Address _____ City _____ Phone _____

I declare that:

1. The nature, purpose, and design of this study have been clearly explained to me by Dr. Lazzari and I have received full answers to all the questions I have asked. Therefore, I consent, by signing this Informed Consent, to participate freely and voluntarily in the study.

2. It has been clearly explained to me that participation in the study is voluntary and therefore I may not take part in the study or I may withdraw from the study at any time I wish and that, if I do so, this will not prejudice any future care and attention from this clinical center and its medical staff.

3. I have had the opportunity to ask questions and reflect on the answers given.

4. I have been informed about any reasonably foreseeable possible risks or discomforts that might result from my participation in the study and have been given sufficient time to decide.

5. I have been informed that I will be notified of both any new data that may change the risks in the future and protocol changes that may affect them.

6. I agree to inform the Study Physician of any medications I am taking and agree to notify any other physician who wishes to prescribe medications for me of my participation in this study. In addition, I agree not to take any such medication without the prior consent of my Study Physician.

7. I agree to inform the Study Physician immediately of any alteration, side effect or adverse event (whether or not evaluated as serious by me) that may arise during the study itself.

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8. I have been informed of my right to have access to the records pertaining to me and to the evaluation expressed by the Ethics Committee to whom I may appeal if I deem it appropriate.

9 I have been informed of the existence of an insurance policy (taken out, in accordance with the laws of the Italian State, with the insurance company Chubb European Group SE, policy no. ITLSQ58614) that provides coverage for any damages that may result from my participation in the study.

10 . I have been informed that in case of any problems or for any further information, I can contact Dr.. _____

Address: _____
Phone._____

11 I am fully aware of and understand my legal rights regarding participation in the study.

Without prejudice to what I specifically signed with this Informed Consent, a copy of which will remain in my possession, I declare that I have carefully read the contents of the Information Sheet and the Information and Manifestation of Consent to the Processing of Personal Data, which are considered an integral and essential part of this and of which I attest that I have acquired a copy sufficiently in advance, and which confirms what was explained to me verbally, and I authorize the Practice Physician to perform the activities described in accordance with the applicable provisions of law.

I consent/do not consent (cross out the option that does not apply) that the Study Physician will inform my family physician of my participation in this study and that, if necessary, my family physician can exchange information about my personal clinical picture.

Subject signature:

_____ date: ___/___/_____

First name and surnme: _____
(block letter)

I confirm that I have fully explained the nature and purpose of the study
SIGNATURE OF Principal Investigator who informed the subject:
_____ date: ___/___/_____

First name and surname: _____
(block letter)

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SIGNATURE OF LEGAL REPRESENTATIVE (when applicable):_____ date: ___/___/_____

First name and surname: _____
(block letter)

NB: In the event that the subject is unable to write, a witness independent of the physician and the Trial Promoter who is able to act as a liaison must be present during the entire discussion regarding informed consent. The witness must personally countersign and date the informed consent statement after the form itself and any other written information has been read and explained to the subject and the subject has given verbal consent to participate in the study. In this case, please complete the following paragraph.:

I the undersigned _____ I testify that Dr. _____ comprehensively explained to Mr_____ the characteristics of the study at hand, as stated in the Information Sheet attached hereto, and that the same, having been given the opportunity to ask as many questions as he deemed necessary, freely agreed to participate in the study.
SIGNATURE OF THE INDEPENDENT WITNESS:

_____ Date: ___/___/_____

First name and surname: _____
(Block letter)

SIGNATURE OF THE INVESTIGATOR who informed the subject.:

_____ Date: ___/___/_____

First name and surname: _____
(block letter)