1. PURPOSE AND OBJECT OF THE INSTRUCTION

The purpose of this instruction is to present the rules for the participation of Volunteers in cosmetology tests confirming the marketing claims of cosmetic products.

2. SCOPE OF APPLICABILITY

This instruction applies to Volunteers participating in cosmetology tests conducted at the Cosmetology Laboratory of J. S. Hamilton Poland Sp. z o.o.

3. RESPONSIBILITIES AND AUTHORISATIONS

POSITION/PERSON RESPONSIBLE	SCOPE OF RESPONSIBILITY
Director of Cosmetology Laboratory Heads of Labs/Units	Supervision of the implementation of the instructions
Research Staff of the Laboratory	Adherence to and fulfilment of the instruction requirements and informing Volunteers about these regulations

4. DEFINITIONS

Definitions are presented on form P-01/DZJ/02-A *Glossary of Terms*, while abbreviations are listed on form P-01/DZJ/02-B *Glossary of Abbreviations*.

5. PROCEDURE DESCRIPTION

The purpose of the tests is to confirm the marketing claims of cosmetic products in a healthy, adult Volunteer or in a minor Volunteer exclusively with parental or legal guardian consent. The testing is conducted according to approved study protocols and procedures of the Cosmetology Laboratory of J.S. Hamilton Poland. Participants in the tests cannot expect any medical benefits from the test carried out.

5.1 Testing Requirements and Limitations

Application and Instrumental Tests: The tested product replaces the previously used product; usage instructions will be provided with each product.

Dermatological Tests: The product is applied during a visit to the centre in the form of a patch test.

UV Tests: The product is applied during a visit to the centre, and the SPF declaration is confirmed in the tests.

Guidelines for the Volunteer:

- Attend mandatory visits at the research centre.
- Do not change cosmetic habits.
- For dermatological and UV tests, do not wet the marked area on the skin, do not attend a pool or sauna.
- Do not change eating habits.
- Avoid excessive sun exposure (unless it is the purpose of the conducted test).
- Do not apply other cosmetic products with a similar purpose at the application site of the tested product.
- You hereby agree not to participate in clinical trials or other cosmetic tests while testing cosmetic products at JS Hamilton.
- You are required to inform the researcher about any event that has occurred during the study (intolerance reaction to the product, illness, accident, use of medications).
- You are required to inform the researcher about any treatment (systemic or local) you receive.
- During the study period, do not breastfeed or plan/be pregnant
  (it does not apply to studies where it is a requirement of the study)
- Participation in the study is not allowed after alcohol consumption.
- I declare that I have active health insurance coverage with the NFZ

5.2 Risks and Possible Adverse Effects

The Sponsor (Client) certifies that the tested product contains active and inactive substances and raw materials whose nature and quantity comply with all national, European and international legal regulations, thereby being safe for human health.

Additionally, cosmetic preparations and raw materials used for their production undergo preliminary verification at the Hamilton Laboratory for compliance of qualitative composition with the lists of substances permitted for use in products that contact the skin (Journal of Laws No. 201, item 2064 of 2004).

However, depending on individual predispositions, there may be a risk of intolerance of the product tested in some people. Any symptoms of intolerance should be reported to the researcher/technician, who decides whether it is necessary to discontinue the use of the product and initiates appropriate treatment if necessary. In some cases it may be necessary to take a photograph.

Any other event (disease, pregnancy, accident, use of medication) must be reported to the technician or to the doctor conducting the tests.

In case of any disturbing situations for the Volunteer (non-specific clinical symptoms, adverse event related to the tested product), the Volunteer is obligated to report such a situation at the Reception Desk.

Contact telephone number:

- reception desk Gdansk +48 695 651 557
- reception desk Gdynia +48 785 348 045

5.3 Participation in the Tests

For the use of the test results, your full participation in the tests is desired; however, you have the right to withdraw from the study at any time. In such a case, you may be asked to inform the researcher, if possible, about the reasons for withdrawal, especially if they relate to the tested product, type of test or conducted measurements. In case of unknown reasons, the test results may be entirely distorted. You will also be able to decide on the use or non-use of the data collected so far. And vice versa, you will be informed by us of the reasons why the tests may be terminated earlier than described in the Testing Schedule.

You have been fully informed about the possibility of being excluded from the tests in case of non-compliance with the participation conditions.

The test procedures are conducted in the spirit of Good Clinical Practice principles.

We guarantee that your anonymity will be maintained during the tests (even if the results are published). According to the principles of Good Clinical Practice, the test report will only include the first two letters of your first name and the first three letters of your last name. Your full data will only appear on the informed consent form and the Volunteers list.

The study documents are available to the Hamilton Laboratory staff, the study Sponsor, and national and foreign control and supervisory institutions, formally bound by professional secrecy. These documents are stored in a folder and then archived.

It is very important that you follow all instructions. The researcher will be happy to provide any additional information.

5.4 Compensation

In tests where compensation is provided to cover travel expenses, it is dependent on the number of visits to the centre, the duration of the tests and the required eligibility characteristics. Full compensation is paid, after signing a contract for specific work, only in case of full participation in the tests. In case of premature termination of participation in the tests or failure to attend all visits, compensation proportional to the number of visits may be paid. If you withdraw from the tests before their completion (not applicable to reactions and serious random events), you will not receive compensation. Compensation will be paid after returning the documentation and completing the required assessments.

In order to obtain all information about the tests, your rights and possible problems related to the tests, please contact Hamilton Cosmetology Laboratory, i.e., phone: 695 651 557 (GDAŃSK) or phone: 885 392 892 GDYNIA
You will be referred to a doctor or technician who will answer all your questions.