Test report

Type of study	**EVALUATION OF THE GYNAECOLOGICAL AND DERMATOLOGICAL ACCEPTABILITY OF A COSMETIC PRODUCT UNDER NORMAL CONDITIONS OF USE**
Product	**Hydra Intima - Vulvar moisturizer cream**
Study Sponsor	**Beautyenigma Lda.** **(Rua Conceiçao Sales, 23 2500-303 - caldas da Rainha)**
Study center	**IPclin Instituto de Pesquisa Clínica Integrada Ltda.** **Rua Leonardo Cavalcanti, 314, Centro** **Jundiaí-SP, Brasil, CEP 13201-013**
Sample Code	**IPC.2024.5663**
Batch/Expiry date	**24H23B / NOT REPORTED**
Receipt date:	**22/11/2024**
Study period	**06/12/2024 – 03/02/2025**
Issue date	**04/02/2025**
Revision date	**11/04/2025** **(Name and sponsor adress update)**

STUDY SUMMARY

Study period	: 06/12/2024 – 03/02/2025
Sample Code	: IPC.2024.5663
Product name	: Hydra Intima - Vulvar moisturizer cream
Product type	: LEAVE-ON
Sponsor	: Beautyenigma Lda.
Test method	: According to the instructions of usage of the sponsor
Panel	: 33 participants
Application area	: Gynaecological area
Methodology	: An initial medical assessment (dermatological and gynaecological assessment) was carried out at the time of the inclusion of the participants to check that there were no initial clinical signs incompatible with the inclusion of the participants. Participants were initially assessed for the presence of fissures, discharge, genital lesions, genital itching and hyperaemia by a gynaecologist. After 21 ± 2 days of using the product, the participants returned to the institution for a final medical assessment of the clinical signs presented and questioning of the sensations of discomfort felt. The data from the medical assessment was recorded in the research notebook. The doctor was available throughout the entire study to assess possible adverse events. After using the product for 21 ± 2 days, the participants returned to the institution and underwent a new gynaecological medical assessment, to check for clinical signs and questioning regarding sensations of discomfort.
Result	: No participants reported feelings of discomfort and no clinical signs were detected after 21 days of product use.
Conclusion	: No participants reported feelings of discomfort and no clinical signs were detected after using the product according to the instructions for use. Therefore, the product supports the claims "Gynaecologically tested " and "Dermatologically tested".

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Rua Pedro Nunes, Bloco C
3030-199 Coimbra
Portugal

+351 239 090 867
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1. INTRODUCTION

The safety of cosmetic products is extremely important, as it constitutes a fundamental requirement for protecting public health, maintaining consumer confidence and complying with regulatory standards. When it comes to cosmetic products for use in the gynaecological area or that may eventually come into contact with the gynaecological area, it is important to assess their gynaecological acceptability in order to prove the product's safety in this area.

Clinical studies aimed at assessing safety in humans can be divided into two main groups: compatibility studies (maximized conditions) and acceptability studies (real conditions of use), such as the gynaecological and dermatological acceptability evaluation study.

In the gynaecological and dermatological acceptability evaluation study, the product must be used in accordance with the instructions on the label for the period and repetitions requested, with the aim of verifying the safety of the product under real conditions of use. This study allows certain safety claims to be substantiated, such as “gynaecologically tested” and “Safe for the gynaecological area”.

These tests must be conducted in accordance with the guidelines and standards for clinical trials, such as the ICH E6 (R2) Good clinical practice - Scientific guideline, an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects, preserving the integrity of the participants. In addition, the Declaration of Helsinki by the World Medical Association (WMA) establishes ethical principles for medical research involving human subjects. According to this declaration, "It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research". The Cosmetics Europe - The Personal Care Association (COLIPA) also provides several orientation guidelines, including the following: “Guidelines for the assessment of skin tolerance of potentially irritant cosmetic ingredients”, “Guidelines for the evaluation of the efficacy of cosmetics products” and “Product test guidelines for the assessment of human skin compatibility”, which are particularly important when conducting these tests.

As well as demonstrating the efficacy and safety of cosmetic products, clinical trials also provide support for claims, informing end consumers of the eventual benefits of the

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product. In that way, safety tests on human subjects, in compliance with legal and ethical requirements, strengthen consumer confidence in cosmetic products. Knowing that products have been rigorously tested before being put on the market increases consumer confidence in their use. This trust is essential for maintaining companies' reputations and protecting consumers' health.

2. OBJECTIVE

The objective of the test is to evaluate the gynaecological and dermatological safety of the investigational product (Hydra Intima - Vulvar moisturizer cream), under normal conditions of use, by gynaecological and dermatological skin acceptability evaluation.

3. METHODOLOGY

3.1. Design of the study

Single-center, single-blind, non-comparative clinical study to prove the safety of cosmetic products.

The study protocol is elaborated by the study center and defined by the study sponsor.

3.2. Research Participant Recruitment Methodology

For the current study, participants registered in the IPclin database were recruited. Participants were selected according to their characteristics and cosmetic habits, and invited to attend the Institution on the first day of the study for an initial assessment by the Investigator, where it is evaluated whether they meet the inclusion criteria and whether there are any incompatibilities listed in the exclusion criteria. Only suitable participants were selected for the study.

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3.3. Participant Selection

CHARACTERISTICS OF THE SELECTED PARTICIPANTS			
No. of participants included in the study	33	**Phototypes (Fitzpatrick)**	I to IV
Gender	F	**Age**	19 to 65

INCLUSION CRITERIA
• Age: 18 to 65 years old. • Gender: female • Phototype: I to IV (according to Fitzpatrick's classification). • Product category user. • Intact skin in the área • Participants with sensitive skin • Ensure not to be part of another clinical study during the research. • Able to follow the guidelines and trustworthy to respect the restrictions of the protocol. • No history of irritation / allergy to the material used in the study. • Agreed to participate in the study and signed the Informed Consent Form (Termo de Consentimento Livre e Esclarecido (TCLE)).

NON-INCLUSION CRITERIA
• Volunteers who do not meet the inclusion criteria. • Irritated skin on test site(s). • Have been intensely exposed to sunlight in the period prior to the study or anticipate UV exposure during the study • Dermographism • Blemishes, marks (e.g. tattoos, scars, sunburn) on the test site(s). • Medication which may affect skin response and/or past medical history. • Presenting skin pathology which may interfere with the aim(s) of the study. • Presenting contact allergy to one of the ingredients of the tested product. • Atopy, skin hyper-reactivity and allergies. • Participation in another simultaneous study. • Participation in a previous study without an appropriate rest period between studies. • Persons deprived of liberty by legal or administrative decision, patients in emergency situation. • Volunteers who refused to give their informed consent. • Pregnancy or lactation.

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- Use of vaginal cream.
- Recent gynaecological surgery.
- Vaginal discharge.

RESTRICTIONS IMPOSED ON PARTICIPANTS
• Not changing diet, cosmetic and hygiene habits or exercise routine during the research. • Not undergo aesthetic or dermatological treatments during the study. • Not apply any product to this area or be exposed to UV radiation. • Avoid tight clothing at the test site to prevent removing the patch and causing irritation. • Medicines prohibited during research: aspirin, antihistamines, corticosteroids, anti-inflammatories and other treatments that reduce or prevent inflammation or allergies.

VOLUNTEERS WITHDRAWALS
Participants will be eliminated for the following reasons: • they do not follow the conditions of the study. • they suffer any illness or accident or develop any condition during the study which could affect the outcome of the study. • they no longer wish to participate in the study (personal reasons). • Serious Undesirable Effect. • Violation of the protocol.

3.4. Ethical Aspects

The volunteers are clearly informed, verbally and in writing, regarding the nature of the study, the timetable, constraints, and possible risks. They give their written informed consent before participation in the study, (Annex 2: "Termo de Consentimento Livre e Esclarecido"). Participants who wish to take part in the study are also informed that it is not for financial gain. They will only be reimbursed for transportation and food expenses.

The test procedures conform to national regulations.

All reasonable care has been taken to avoid causing excessive skin reactions or other adverse health effects in the participants during the study.

Safety procedures are in place in the event of any unexpected/adverse reactions, including appropriate medical cover.

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Rua Pedro Nunes, Bloco C
3030-199 Coimbra
Portugal

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Confidentiality

The anonymity of the volunteers is respected, no personal records have been kept apart from the ones required for the test. Each volunteer can be identified by the Investigator, all the persons in charge of the study, thanks to his personal volunteer's code.

3.5. Investigational product

PRODUCT NAME	: Hydra Intima - Vulvar moisturizer cream
SAMPLE CODE	: IPC.2024.5663
PRODUCT TYPE	: LEAVE-ON
BATCH	: 24H23B

3.6. Application of the Investigational Product

The investigational product was given to the participants on the first day of the research to be used at home for 21 ± 2 days according to the instructions of use informed by the Sponsor.

How to use: *"aplicar o produto externamente na zona vulvar duas vezes por dia, preferivelmente de manhã e à noite, antes de deitar-se"*

3.7. Dermatological Assessment

An initial medical assessment was carried out at the time of the inclusion of the participants to check that there were no initial clinical signs incompatible with the inclusion of the participants.

After 21 ± 2 days of using the product, the participants returned to the institution for a final medical assessment of the clinical signs presented and questioning of the sensations of discomfort felt.

The data from the medical assessment was recorded in the research notebook. The doctor was available throughout the entire study to assess possible adverse events.

The results are evaluated according to the following table:

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REACTION	RESULT	PONCTUATION
Absent	Negative (-)	0
Mild erythema	Doubtful (?)	1
Clear erythema	Positive (+)	2
Erythema + Oedema + Papules	Positive (++)	3
Erythema + Oedema + Papules + Vesicles	Positive (+++)	4

If the investigating doctor finds a positive result, the application of the sample in question will be suspended and the research participant will be retested. For these situations, the adverse event form must be completed until the event is over. The form must be completed in accordance with the results interpretation table.

In order to evaluate the results, no adverse events are expected, i.e., the product will be considered non-irritating if it triggers a maximum of 3% of grade 1 (+) reactions in relation to the total number of applications or up to 2% of grade 2 (++) reactions.

If the product presents a single case of grade 3 reaction (+++), or a higher incidence of allergy as described above, it will be considered at risk for the development of allergy in humans and consequently inadvisable for use.

Reactions at the test site that remain the same or increase after 96 hours are suggestive of sensitization. Those that fade after 24 hours of removing the patch are possibly due to the irritant action of the substance tested (Wahlberg, et. al., 2006).

3.8. Gynaecological Assessment

An initial gynaecological assessment was carried out at the time of the participants' inclusion to check that there were no initial clinical signs incompatible with the participants' inclusion. Participants were initially assessed for the presence of fissures, discharge, genital lesions, genital itching and hyperaemia by a gynaecologist.

After using the product for 21 ± 2 days, the participants returned to the institution and underwent a new gynaecological medical assessment, to check for clinical signs and questioning regarding sensations of discomfort.

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The data from the medical assessment was recorded in the research notebook. The doctor was available throughout the study to assess possible adverse events.

The results were evaluated as follows:

- Sensations of discomfort: participants were asked about sensations of discomfort in parallel with the clinical examination. The sensations of discomfort were reported (examples: heating, tingling, itching, pulling, burning, etc.) and classified as mild, moderate or intense/severe.

- Clinical signs: have been reported (e.g. erythema, oedema, vesicle, blister, papule, crust, dryness, dyschromia, macule). The intensity of erythema and oedema was assessed according to an ordinal scale: mild, moderate, severe. The appearance of the erythema was defined as: diffuse, punctuated. The importance of the number of vesicles was assessed according to an ordinal scale: 1 to 2 vesicles, more than 2 vesicles. Bubbles and macules were counted. Crusts, dryness and colour changes (dyschromia) have been described. The importance of dryness and dyschromia is assessed according to an ordinal scale: mild, moderate, severe.

The causal link between the reactions to the product was investigated.

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Rua Pedro Nunes, Bloco C
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4. RESULTS

No. of participants involved	33	**No. of participants who completed the study**	33

No. of participants who dropped out	0	**Reference and reason for dropouts**	Not applicable
No. of excluded participants	0	**Reference and reason for excluded participants**	Not applicable

Dermatological Acceptability:

No participants reported feelings of discomfort and no clinical signs were detected after 21 days of product use.

Gynaecological Acceptability:

No participants reported feelings of discomfort and no clinical signs were detected after 21 days of product use.

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5. CONCLUSION

In the study entitled "EVALUATION OF THE GYNAECOLOGICAL AND DERMATOLOGICAL ACCEPTABILITY OF A COSMETIC PRODUCT UNDER NORMAL CONDITIONS OF USE", referring to the product Hydra Intima - Vulvar moisturizer cream, code IPC.2024.5663, sent by the Sponsor Beautyenigma Lda., it can be concluded that:

No participants reported feelings of discomfort and no clinical signs were detected after using the product according to the instructions for use.

Therefore, the product supports the claims "Gynaecologically tested " and "Dermatologically tested".

NOTE 1: The result refers to the sample received.

NOTE 2: Sampling was carried out by the Sponsor of the study.

NOTE 3: The condition under which the test was carried out guarantees the traceability of the data generated.

NOTE 4: Partial reproduction of this Test Report is prohibited.

Archiving: A sample of the product is kept for a period of 1 month from the end of the research and the study reports are kept for 5 years.

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Rua Pedro Nunes, Bloco C
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6. REFERENCES

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3030-199 Coimbra
Portugal

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7. APPROVAL

The study concerned by this report was carried out, according to the experimental protocol and the quality plan of the IPclin and follows the good clinical practices.

All the observations and data recorded during this trial are reported in this study report.

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Principal Investigator: Dr. Luiz Antonio Cipolotti (Gynaecologist – CRM: 112.413)	Co-Investigator: Dra. Roberta Pontes Farath (Dermatologist – CRM: 112.458)

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Co-Investigator: Cassiano Carlos Escudeiro (Chemist - CRQ: 04153268 IV Região)	Clinical Investigation Report verified by: Margarida Lindo (MSc Pharmaceutical Sciences)

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Rua Pedro Nunes, Bloco C
3030-199 Coimbra
Portugal

+351 239 090 867
info@pharmilab.eu
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ANNEX 1 – CHARACTERISTICS OF THE RESEARCH PARTICIPANTS

Participant Ref.	1	2	3	4	5	6	7	8	9	10
Name initials	MB	LSS	CSF	GMM	AMH	ASS	RSOS	AB	MSL	MMA
Sex (M or F)	F	F	F	F	F	F	F	F	F	F
Age	27	26	65	49	42	28	36	46	28	49
Phototype (I to IV)	IV	III	III	I	III	II	I	III	III	III
Participant Ref	11	12	13	14	15	16	17	18	19	20
Name initials	JSGT	LAS	JOP	PASP	MA	AC	TLV	SGMD	SASS	MVFS
Sex (M or F)	F	F	F	F	F	F	F	F	F	F
Age	28	37	25	44	60	43	27	49	39	48
Phototype (I to IV)	III	III	II	III	I	III	III	II	III	I
Participant Ref	21	22	23	24	25	26	27	28	29	30
Name initials	AS	MMM	PB	VCS	MVSS	ABS	MAS	DHR	MFC	EPS
Sex (M or F)	F	F	F	F	F	F	F	F	F	F
Age	49	49	38	28	19	30	35	30	38	33
Phototype (I to IV)	III	III	II	IV	III	I	III	IV	III	III
Participant Ref	31	32	33							
Name initials	PCO	MFS	PXJ							
Sex (M or F)	F	F	F							
Age	28	20	34							
Phototype (I to IV)	IV	III	IV							

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ANNEX 2 – INFORMED CONSENT FORM

"TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO"

AVALIAÇÃO DA ACEITABILIDADE DERMATOLÓGICA E GINECOLÓGICA DE PRODUTOS COSMÉTICOS

- ✓ Você está sendo convidado a participar de uma pesquisa. Pedimos que entenda detalhadamente todas as etapas e, se concordar, assine este termo de consentimento.
- ✓ Todas as dúvidas surgidas durante e após a pesquisa clínica serão prontamente esclarecidas.

JUSTIFICATIVA DA PESQUISA
✓ Justifica-se a realização do ensaio pela necessidade de comprovar, em condições reais de uso, a segurança do produto investigacional em seus usuários finais, seres humanos.

OBJETIVO DA PESQUISA
✓ Avaliar a segurança dermatológica e ginecológica de um produto cosmético, em condições normais de uso.

PROCEDIMENTO DO TESTE
✓ A pesquisa será realizada em 30 pessoas, sendo no mínimo 30 participantes avaliáveis; ✓ No primeiro dia você virá até a Instituição para uma avaliação clínica (avaliação pelo médico dermatologista e pelo ginecologista) da sua região íntima. ✓ Caso você atenda aos critérios necessários para o estudo, você receberá o produto para usar em casa durante 21 dias conforme as orientações recebidas na Instituição. ✓ Depois de 21 dias, você deverá voltar à instituição para realizar a última avaliação pelos médicos (dermatologista e ginecologista).

EXIGÊNCIAS DURANTE O PERÍODO DA PESQUISA
✓ Você deverá seguir algumas exigências durante o período da pesquisa e somente se concordar deverá assinar este termo de consentimento livre e esclarecido: ○ Não estar grávida ou com intenção de engravidar durante a pesquisa; ○ Não participar em nenhuma outra pesquisa clínica em outra Instituição Proponente de Pesquisa durante a pesquisa; ○ Não alterar hábitos cosméticos, de higiene, de dieta e de exercícios; ○ Não alterar o tratamento hormonal, nem o método contraceptivo medicamentoso; ○ Não utilizar medicações de uso tópico ou sistêmico: qualquer anti-inflamatório; antialérgicos; imunossupressores (medicamentos que bloqueiam a resposta do sistema de defesa); vitamina A ácida e seus derivados; ○ Não realizar tratamento estético, com esteticista ou médico Dermatologista; ○ Não permitir que outra pessoa use o seu produto da pesquisa; ○ Não aplicar produtos parecidos na região de aplicação do produto da pesquisa;

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- Em caso de tratamento médico durante a pesquisa, qualquer que seja, informar imediatamente ao responsável pela pesquisa;
- Evitar prática intensiva de esportes;
- Evitar exposição solar intensa, banhos de mar ou piscina durante toda a pesquisa;
- Não se vacinar durante a pesquisa.

- ✓ **CADA VISITA TEM DURAÇÃO DE 30 MINUTOS. OS HORÁRIOS E DIAS AGENDADOS DEVEM SER RESPEITADOS. OS ATENDIMENTOS ACONTECERÃO EM ORDEM DE CHEGADA.**
- ✓ Os resultados do questionário de avaliação do produto poderão ser divulgados, mas de forma anônima para não expor o participante (quando aplicável).
- ✓ Todos os itens acima foram lidos e esclarecidos, em voz alta, para os participantes da pesquisa.

DESCRIÇÃO DOS DESCONFORTOS E RISCOS PREVISÍVEIS

- ✓ O grau dos riscos associados à pesquisa pode variar de pessoa para pessoa, levando em consideração as diferentes características fisiológicas e pessoais dos participantes. Existem desconfortos e riscos mínimos para o participante da pesquisa, entretanto, como qualquer produto, poderá causar reações inesperadas como "vermelhidão", "inchaço", "coceira" e "ardor" nos locais de aplicação deste.
- ✓ Todos os produtos passaram por um teste pré-clínico antes de serem submetidos para a pesquisa em questão, onde foi confirmado a não irritação e corrosão da pele.

MEDIDAS DE PRIMEIROS-SOCORROS:

- ✓ Contato com a pele: Lavar com água corrente. No caso de irritação ou sensibilização procurar auxílio médico.
- ✓ Contato com os olhos: Lavar com água corrente. No caso de irritação procurar auxílio médico.
- ✓ Ingestão: Em caso de ingestão acidental procurar auxílio médico.

BENEFÍCIOS ESPERADOS

- ✓ Sua participação nesta pesquisa não trará nenhum benefício direto a você, porém participar desse estudo trará um benefício indireto, onde possibilitará a verificação da segurança de um produto de uso íntimo, garantindo à comunidade um produto seguro.

FORMA DE ACOMPANHAMENTO E ASSISTÊNCIA DO PARTICIPANTE DA PESQUISA

- ✓ Garantimos que qualquer reação adversa provocada pelo produto em teste será acompanhada pelo médico dermatologista e/ou especialista responsável pelo projeto e que, se necessário, será fornecida a medicação adequada, atendimento médico, locomoção até o hospital de retaguarda, **Hospital de Caridade São Vicente de Paulo**, é localizado na R. São Vicente de Paulo, 223 - Centro, Jundiaí - SP, 13201-625, onde será realizado o atendimento e serão pagas pela Instituição a internação e todas as demais despesas que se fizerem necessárias para a garantia da saúde e do bem-estar pleno da sua participação. Em complementação, poderá ser possível a realização de um teste complementar de acordo com as modalidades planejadas pelo responsável da pesquisa, para que seja entendida a reação adversa provocada pelo produto teste.

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Rua Pedro Nunes, Bloco C
3030-199 Coimbra
Portugal
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- ✓ Garantimos que caso você apresente uma gravidez não planejada ao longo da pesquisa será acompanhada ao longo da gestação e pelo tempo que for necessário após o nascimento do bebê.
- ✓ Garantimos o seu direito à solicitação de indenização conforme o Código Civil Brasileiro.

CONTATO COM O PESQUISADOR E COM O CEP (COMITE DE ÉTICA EM PESQUISA)

- ✓ Em caso de dúvida ou intercorrência, você deve procurar imediatamente o centro de pesquisa ou, então, entrar em contato, diretamente, com o pesquisador responsável ou qualquer membro da equipe através dos telefones abaixo.
- ✓ Pesquisador responsável: Andrea Trugilo Jurado
- ✓ Endereço: Rua Dr. Leonardo Cavalcanti, 314 – Centro- Jundiaí/SP - 13.201-013. Horário de Funcionamento: Segunda a Sexta-feira – 08h às 17:30h ou telefone: 11 97030-2777 (atendimento 24h)

GARANTIA DE RECUSA À PARTICIPAÇÃO OU SAÍDA DA PESQUISA

- ✓ Estou livre para interromper a qualquer momento minha participação na pesquisa se assim eu desejar ou a critério do pesquisador, o que não me causará nenhum prejuízo.
- ✓ Estou livre para não aceitar a minha participação nesta pesquisa.

GARANTIA DE SIGILO

- ✓ Meus dados pessoais serão mantidos em sigilo e os resultados gerais obtidos na pesquisa serão utilizados apenas para alcançar os objetivos do trabalho, expostos acima, incluída sua publicação na literatura científica especializada.

GARANTIA DE ENTREGA DE VIA

- ✓ Este Termo de Consentimento é feito em duas vias, sendo que uma via permanecerá com você (participante da pesquisa) ou seu representante legal e a outra via sob com o pesquisador responsável, ou pela pessoa por ele delegada.

RESSARCIMENTO E DESPESA

- ✓ Você não receberá nenhuma compensação financeira relacionada à sua participação neste estudo. Da mesma forma você não terá nenhuma despesa pessoal em qualquer fase do estudo, incluindo exames e consultas. Durante o período de sua participação, se houver qualquer despesa adicional de sua parte em relação à condução ou alimentação, você será reembolsado.

Assinatura do participante: _____ Data: _____/____/_____

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info@pharmilab.eu
www.pharmilab.eu

Concordo em participar da pesquisa clínica **"AVALIAÇÃO DA ACEITABILIDADE DERMATOLÓGICA E GINECOLÓGICA DE PRODUTOS COSMÉTICOS"** e declaro ter sido esclarecido sobre todos os itens acima.

Concordo que um representante do Patrocinador possa estar presente durante algumas etapas da pesquisa.

- Eu declaro não ter me exposto a risco de gravidez nos últimos 3 meses antes do início da pesquisa;

- Não estou amamentando, grávida ou planejando gravidez durante a pesquisa (para mulheres em idade fértil);

- Eu não iniciei ou alterei a contracepção estrógeno-progesterona ou tratamento hormonal, dentro de 3 meses antes da pesquisa ou prevendo iniciar ou alterar durante a pesquisa.

TESTEMUNHA

(Preencher apenas quando o participante não for alfabetizado)

Eu, _____

(Nome completo, sem abreviação)

Assinatura da testemunha:_____ Data: _____/____/_____

Ass. do Resp. por aplicar o TCLE: _____ Data: ___/___/___

IPclin EUROPE

Rua Pedro Nunes, Bloco C
3030-199 Coimbra
Portugal

+351 239 090 867
info@pharmilab.eu
www.pharmilab.eu