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Analisi biologiche e chimiche
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MICROBIOLOGICAL ANALYSIS

BATCH CONTROL

• **Microbiological analysis** on ingredients and finished products (cosmetics, medical devices and similar items): total viable bacteria count, yeasts and moulds count according to methods ISO (21149 e 16212), European Pharmacopoeia / USP, Cosmetics Europe, PCPC; Research of specific microorganisms according to ISO (21150, 22717,22718, 18416) European Pharmacopoeia /USP, Cosmetics Europe, PCPC .

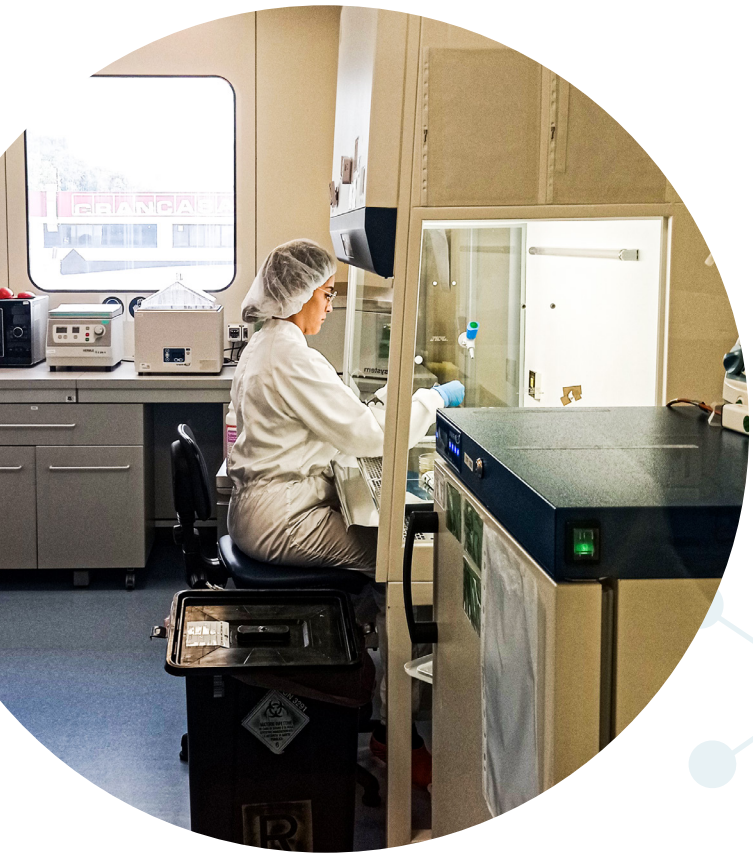
• **Validation of microbiological analytical methods** on specific matrix according to ISO 11930, European Pharmacopoeia,USP and PCPC.

• **Bioburden on MD** according to UNI EN 11737-1 and sterility assays.

• **Bacterial endotoxins search (LAL Test)** according to USP and European Pharmacopoeia.

• **Isolation and identification of contaminant strains** in products or in the manufacturong premises through DNA /RNA sequencing or o MALDI-TOF or morphological analysis (moulds).

• **Test on surgical masks** UNI EN 14683:2019 annex D Bioburden; UNI EN 14683:2019 annex B ; bacterial filtration efficacy (BFE) according to ISO 14683.



PRODUCTS DESIGN (Cosmetics, Medical, Devices, Disincectants, Biocides, Textiles, etc.)

• **Challenge test** (Test for the efficacy of preservative system) according to methods ISO 11930, European Pharmacopoeia, USP, FDA, Cosmetics Europe, PCPC.

• **Isolation and identification** of contaminant strains of products or manufacturing premises to add them in customized challenge tests.

• **Evaluation of D value** for the determination of PAO (Period After Opening).

• **In-use test in vitro** or on volunteers to evaluate the microbiological stability and PAO

• **Risk assesment for microbial contamination** of cosmetic products according to ISO 29621.

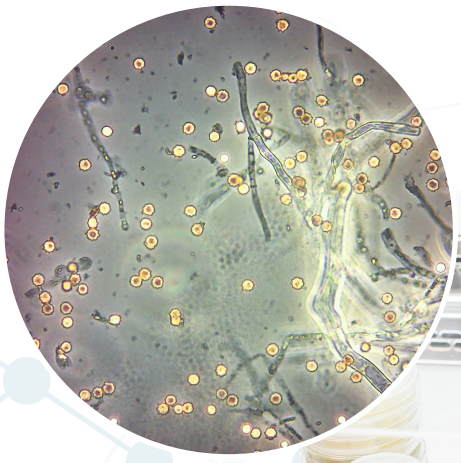
• **Evaluation of the antimicrobial efficacy** of chemical disinfectants and antiseptics according to UNI EN 14885 in medical, domestic, istitutional and veterinary field.

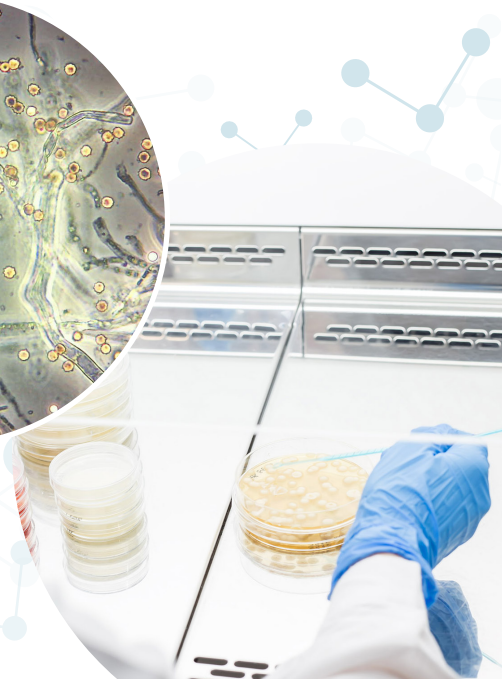
• **Evaluation of specific antimicrobial efficacy** of products or ingredients towards strains of bacteria, fungi, viruses of dermatological or cosmetic interest (MIC, MBC, contact inhibition).

• **Antibacterial activity test** of textiles according to ISO 20645, ISO 20743 and ISO 22196

• **Test for the evaluation** of the action of microfungi on textile products according to UNI EN 1411.

• **Virucidal activity of chemical disinfectants,** antiseptics and similar products according to UNI EN 14476, UNI ISO 16777, ISO 21702, ISO 18184 (more additional virus strains, like coronavirus, are also available).





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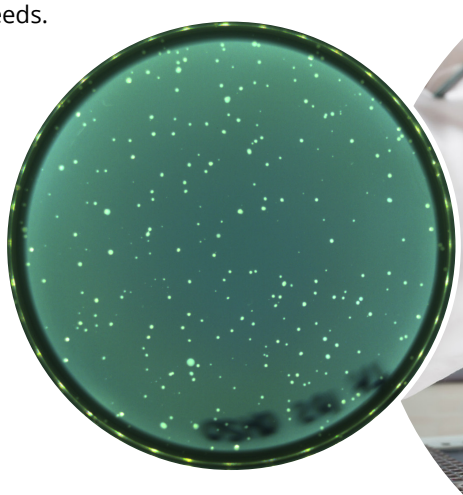
MICROBIOLOGICAL ANALYSIS

- **Evaluation of the efficacy of finish products** or active ingredients on the skin microbiome modification through in vitro preliminary assays and test on slected panel of human volunteers.
- **Search for bacterial endotoxins (LAL Test)** according to USP and UE Pharmacopoeia.
- **Evaluation of the efficacy of environmentale disinfection** by aerodisperse methods according to UNI EN 17272:2020.
- **Evaluation of the modification of bacterial adhesion** towards mammal cells by medical devices, supplements or active ingredients.
- **Mutagenesis assay (test di Ames)** according to OECD 471.
- **Design of customized testing protocols** and method validations on the bases of the sponsor's needs.

CONTROL OF MANUFACTURING PREMISES

- Environmental analysis of aerodisperse microorganisms by air sampling with SAS SUPER IAQ "Surface Air System".
- Environmental analysis of the microbial contamination of surfaces in manufacturing plant, equipments and laboratories.
- Validation of cleaning and sanitisation procedures and protocols for manufacturing plant and premises in cosmetic and biomedical facilities.
- Design of testing protocols and customized validations on specific needs of the client.



Quality systems and certifications: GLP (Italian Ministero Salute), ISO 17025, ISO 13485, ISO 9001, GMP (Montreal site).

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CHEMICAL-PHYSICAL ANALYSIS FOR QUALITY CONTROL

• **Instrumental analysis** by HPLC and UHPLC with UV/DAD/RID detector.

• **Instrumental analysis** by GC-FID, GC-MS, ICP-OES, FT-IR/UATR, UV-VIS.

• **Quantification** of active ingredients and preservatives in cosmetics and medical devices.

• **Analysis** of multiresidal impurities and of trace contaminants in finished products and ingredients, like for example: phtalates, nitrosamines, VOC, substances listed in annex II of regulation (CE) 1223/2009.

• **Chemical characterization of medical devices** according to ISO 10993-18: extractables and leachables

• **"Paraben free":** ultra-traces analysis to support the claim "Paraben-Free" in finished coasmetic products, control of preservatives residure on manufacturing plants and « cleaning validation".

• **Allergenes:** analysis of allergenes in cosmetic finished products and ingredients from natural sources.

• **"Nickel Tested":** control on product batches and intermediates bulks to support the claim "Nickel Tested".

• **Metals:** analysis of inorganic contaminants in finished products and raw materials; toxic metals like Hg, Cd, As, Pb and sensitising metals like Ni, Cd, Co, Cr. Cosmetic relevant metals: As, Sb, Cd, Hg, Ni, Co, Cr, Pb e Cr VI.

• **Metals:** ICH guideline Q3D (R2) on elemental impurities - Table 5.1: elements to be considered in the risk assessment – oral, parenteral and inhalation exposure.

• **Release test in artificial sweat or saliva** for the detection of sensitising metals in cosmetic anhydrous and solid products; Release test in artificial sweat or saliva according to ISO 10993-12 for substances or impurities in medical devices.

• **Validation of analytical methods** according to ICH Guidelines for medical devices and for products to be marketed on the USA and European market.

• **Test and analysis to support specific claims**, customized according to the sponsor's needs.

• **Test and analysis** to support "cleaning validation" processes.

• **Percutaneous and permucosal** absorption test through Franz cells (OECD 428 and FDA methods): many epithelial and epidermis human models as well as synthetic membranes.

• **Stability assays** according to ICH for medical devices, to CIPAC for PMC e Biocides, to ASTM or PCPC for cosmetics. Chemical-physical and microbiological analysis.

• **Packaging compatibility.**

• **Photostability of sun products** with SUN TEST – sunscreens analysis and evaluation of decay before and after Uv exposure.

• **E-cigarettes and aromes:** safety and toxicity analysis.

• **Botanical extracts analysis.**

• **Control of manufacturing** for batches of PMC and Biocides.

• **Quality control:** analysis of osmolarity, surface tension, viscosity, density, drop point, softening point etc. on ingredients, bulks and manufacturing product batches.

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CHEMICAL-PHYSICAL ANALYSIS AND ASSAYS TO SUPPORT PRODUCT DEVELOPMENT

• **Stability assays** according to ICH for medical devices, to CIPAC for PMC e Biocides, to ASTM or PCPC for cosmetics. Chemical-physical and microbiological analysis.

• **Compatibility with packaging,** analysis of impurities and contaminants released or absorbed by the packaging components.

• **Photostability of sun products** with SUN TEST – sunscreens analysis and evaluation of decay before and after Uv exposure.

• **Chmical characterization of medical devices** and components of for BEP/BER (Biological Evaluation Plan and Report).

• **Metals:** ICH guideline Q3D (R2) on elemental impurities - Table 5.1: elements to be considered in the risk assessment – oral, parenteral and inhalation exposure.

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• **Test and analysis to support specific claims,** customized according to the sponsor's needs.

• **Test and analysis** to support "cleaning validation" processes development.

• **Percutaneous and permucosal absorption test through Franz cells** (OECD 428 and FDA methods): many epithelial and epidermal human models available as well as synthetic membranes to select according to the product destination and use. Identification and development of the analytical method.

• **E-cigarettes and aromes:** safety evaluation and toxicological analysis for components and ingredients with in-use simulation.

• **Characterisation of botanical extracts** and development of the extraction method for the industrial scale-up.

• **Mucoadhesion assay:** adhesiveness test to verify nd compare the physical adhesion properties of medical devices and products aimed to be used on mucosae.

• **Compatibility** with condoms according to ASTM D6771 o ISO 19671 standards through traction and explosion tests.

• **In vitro UVA pf and broad spectrum UV** protection according to ISO 24443: and to Boots Star Rating; in vitro water resistance and variants.

• **In vitro blue light protection** and far UVA protection evaluations.

• **Trichological tests in vitro on human hair** locks to support customized cosmetic claims Test like for example: resistance to break, combability, color strenght and many others.

• **Customized tests on hair treatments** according to the sponsor's needs.

• **UV protection test for Medical adhesive** and Textiles according to EN 13758.

Certificazioni e sistemi di qualità: BPL (Ministero Salute), ISO 17025, ISO 13485, ISO 9001.

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IN VITRO TEST

SAFETY AND TOXICOLOGICAL ASSAYS

• **Cytotoxicity assays on cosmetics,** ingredients and medical devices according to UNI EN ISO 10993-5.

• **Predictive assays for skin irritation** on cell monolayers (fibroblasts, keratinocytes).

• **Irritation test** on 3D reconstituted human epidermis (OECD439).

• **Skin irritation test** on 3D reconstituted human epidermis for medical devices (ISO 10993-23).

• **Irritation tests** on 3D reconstituted human epithelia (vaginal, gengival, oral, respiratory...).

• **Skin corrosion tests** (OECD 431, 435).

• **Eye irritation tests** (OECD 491, 492, 492B, 496).

• **Eye corrosion test** (OECD 460).

• **Skin sensitisation assay OECD 442D** (keratinosens).

• **Skin sensitisation assay OECD 442E** (IL-8 Luc Assay, hCLAT, GARDTM).

• **Skin sensitisation assay** on 3D reconstitued human skin (IL-18 RHE Assay, SENS-IS).

• **Phototoxicity assay** (OECD 498 on 3D epidermis).

• **Phototoxicity assay** (OECD 432 on cell monolayers).

• **Mutagenesis assay** (Ames) (OECD 471): screening and full test.

• **Ecotoxicity assay on Daphnia Magna** (OECD 202) and algae (OECD 201).

• **Biodegradability test** (OECD 301F).

• **Carcinogenesis in vitro assay** (OECD guidance document n. 231).

• **Mutagenesis assay in mammal cells** (Comet assay).

• **Assays for the evaluation** of hormonal endocrin disr uptor effects (OECD 456, 458, 455).

• **Percutaneous absorption test with Franz cells Test** on human reconstituted 3D epidermis and epithelia, on ex vivo epidermis, on wounded epidermis etc.

• **Cytotoxicity assays** to aestimate in vitro the oral LD50 value (OECD guidance document 129).

EFFICACY TESTS

• **Antioxidant and anti– free radicals activity** on skin-derived cells (ROS analysis on keratinocytes and fibroblasts) following chemical or physical stress.

• **Direct antioxidant activity assay** (es ORAC TEST).

• **Antiage activity/derma ridensifying activity:** mitogen effect, stimulation of the proteins synthesis, increase of the synthesis of proteins of the extracellular matrix (collagen, elastin, fibronectin, etc).

• **Barrier effect test** on human 3D reconstituted epithelia and epidermis.

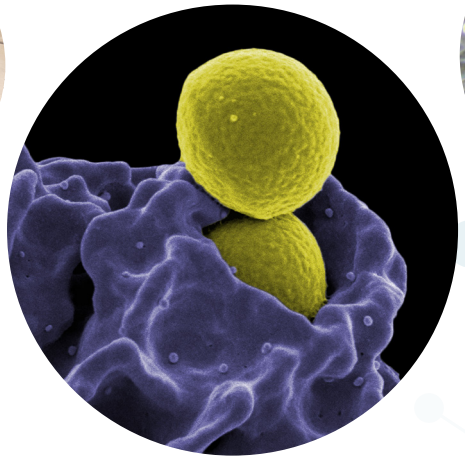
• **Evaluation of the keratolitic effect** with test on human 3D reconstituted epidermis.

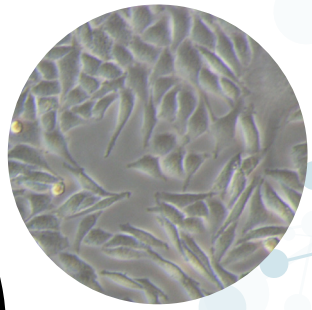
• **Wound healing activity assays** on endothelial cells and fibroblasts (healing products and ingredients, anti-stretchmarks products).

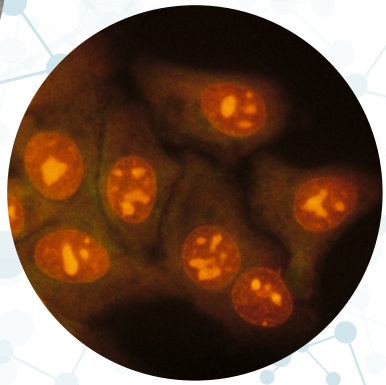
• **Test for the evaluation of the effect** on melanogenesis (increase/reduction of the melanine synthesis by whitening or tanning products) both on monolayer cells or on 3D human in vitro pigmented epidermis.

• **Assay for the evaluation of tirosinase gene expression** on monolayer cells.

• **Assay for the direct evaluation of the modulation of enzimatic activity** (i.e. Tirosinase, Acetilcolinesterase, Collagenase and other metalloproteinases).







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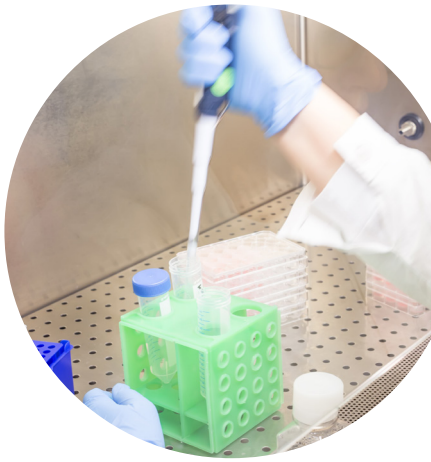
IN VITRO TEST

- **Anti-inflammatory activity assays** on human 3D reconstituted epithelia and epidermis.
- **Test to evaluate the immune response** through analysis of specific mediators (i.e. Histamine, IL-1α, TNF-α) to evaluate anti-itching activity, inhibition of sensitisation, immunistimulating activity etc.
- **Test for the evaluation** of cell senescence.
- **Test for sebum control activity** (inhibition of lipase).
- **Evaluation of the inhibition of 5-α reductase enzyme** (hair growth, acne, sebum regulation).
- **Skin hydrating activity of cells** in monolayer or 3D reconstituted epidermis.
- **Anti-pollution efficacy** against smog and toxic chemicals.
- **Lipolitic activity on adipocytes.**
- **Inhibition of neo-angiogenesis** through analysis of VEGF expression (i.e.anti-couperose products).
- **Test to support barrier effact** towards heat (IR) on human 3D reconstituted epidermis.
- **Percutaneous absorption tests with Franz cells** on human 3D reconstituted epithelia and epidermis, on ex-vivo epidermis, on wounded epidermis to evaluate the permeation of ingredients , the efficacy of carriers or the barrier effect against permeation.
- **In vitro test of products for acne rosacea treatment** through the analysis of gene expression of markers involved in skin inflammation and linked to rosacea.
- **Customized protocols and R&D projects.**

PHYSICAL PERFORMANCE IN VITRO ASSAYS

- **Mucoadhesion assay:** gravimetric test to verify and compare the physical adhesion properties of medical devices and products aimed to be used on mucosae.
- **Compatibility with condoms** according to ASTM D6771 o ISO 19671 standards through traction and explosion tests.
- **In vitro UVApf and broad spectrum UV protection** according to ISO 24443:2021 and to Boots Star Rating; in vitro water resistance and variants.
- **In vitro blue light protection and far UVA protection evaluations.**
- **Trichological tests in vitro on human hair locks** to support customized cosmetic claims Test like for example: resistance to break, combability, color strenght and many others.
- **Customized tests on hair treatments** according to the sponsor's needs.

Quality systems and certifications: GLP (Italian Ministero Salute), ISO 13485, ISO 9001.



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COSMETOLOGICAL AND CLINICAL TESTING

SAFETY TESTING

• **Patch test, Repeated Insult Patch test,** Patch test on sensitive skin, for cosmetics and similar products.

• **Evaluation of sensitisation risk** and claim hypoallergenic with HRIPT (Human Repeat Insult Patch Test) on cosmetic products.

• **Dermatological, ophtalmological and gynaecologicaliln -use tests** on voluteers to evaluate the tolerabilty of cosmetic products.

• **Sun product tests:** SPF and Water Resistant (ISO 24444: 2019 Amd 1.2022, ISO 16217/18861:2020 FDA vol 76 n° 117 of 17 June 2011) SPF UVA PPD according to ISO 24442: 2022, test for SPF long lasting, test for SPF according to Australian method AS/NZS 2604: 2021.

• **SPF on wet skin, SPF Water/Sand/Sweat resistance, SPF persistence for sun products**.

• **Photo-patch test** for cosmetic products.

EFFICACY AND PERFORMANCE TESTING

• **Tests for short and log-term** skin moisturization throug corneometry and/or TEWL measures.

• **In-use test on sleceted human volunteers panels** for the evaluation of the efficacy of cosmetic products under medical supervision (dermatologist, allergologist, gynaecologist, ophtalmologist, , dentist etc.).

• **Sensorial analysis** and administration of questionnaires to selected panels of healthy volunteers.

• **Anti-wrinkles test through quantitative analysis** of profilometry and skin imaging with 3D blue laser scanner (DERMA TOP-Blue) or with 3D imaging (ANTERA).

• **Skin elasticizing, firming/tonifying activitiy tests** through skin probes.

• **Evaluation of skin barrier performance** (TEWL - Trans Ephitelial Water Loss), Arm Wash Test.

• **Test for anti-eye and anti-eye circles activity** through volumetric analysis , skin dermatograhy and skin colorimetry.

• **Skin depigmentation, belaching and lighteningh tests** through Chromameter or Antera imaging.

• **Skin darkening and increase of tanning speed test.**

• **Anti -cellulitis activity test** through Antera or Derma TOP-blue .

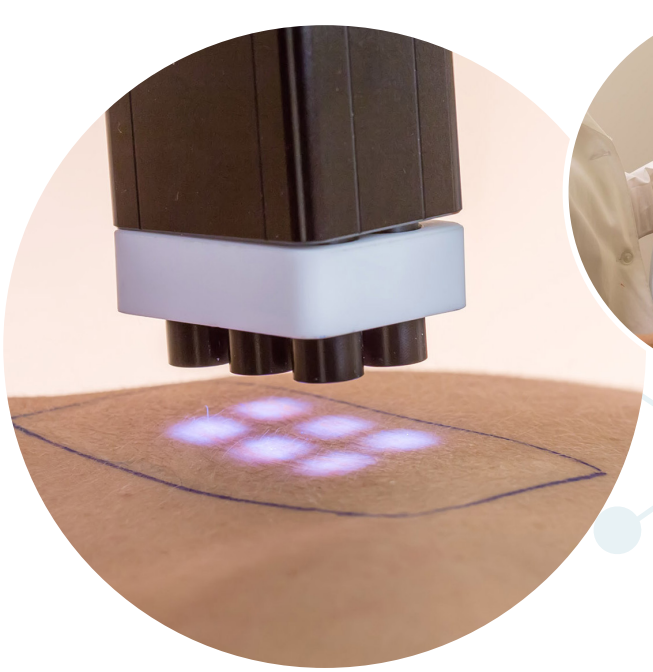
• **Test for skin sebum reduction** through Sebometer.

• **Comedogenesis assays.**

• **Anti perspirant activity test,** 24 h or 48 h lasting (FDA method with sauna) and deodorizing activity (Sniff Test).

• **Skin soothing activity test** with irritation induced by chemicals or with UV-rays

• **Long-lasting test for make-up** for face, lips and eyelash.



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COSMETOLOGICAL AND CLINICAL TESTING

- **Lip-volumizing activity test** for lip and eyelash make-up.

- **Efficacy tests for trichological products:** anti-dandruff activity, hair fall prevention and hair growth activity with TrichoScan, hair viability , color strenghtness etc.

- **Test for Sun products:** SPF , Water Resistant and Very water Resistant (ISO 24444: 2019 Amd 1:2022, ISO 16217/18861:2020, FDA vol 76 n° 117 of 17 June 2011), SPF UVA PPD according to ISO 24442: 2022, SPF long lasting Test, test SPF according to Australian method AS/NZS 2604: 2021.

- **SPF on wet skin, SPF Water/Sand/Sweat resistance, SPF persistence.**

- **Evaluation of the antimicrobial efficacy** of chemical disinfectants and antiseptics according to UNI EN 14885 in medical, domestic, istitutional and veterinary field

- **Usability tests** for medical devices

- **Efficacy studies for supplements** for healthy skin, mucosae and cutaneous annexes.

OTHER STUDIES

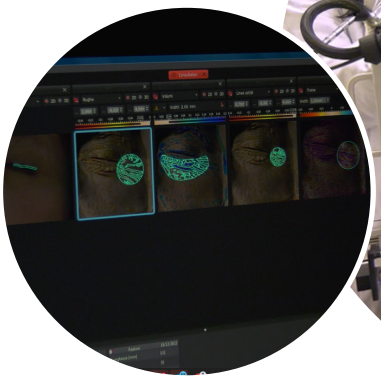
- **Post-marketing clinical studies** on medical devices according to UNI EN ISO 14155.

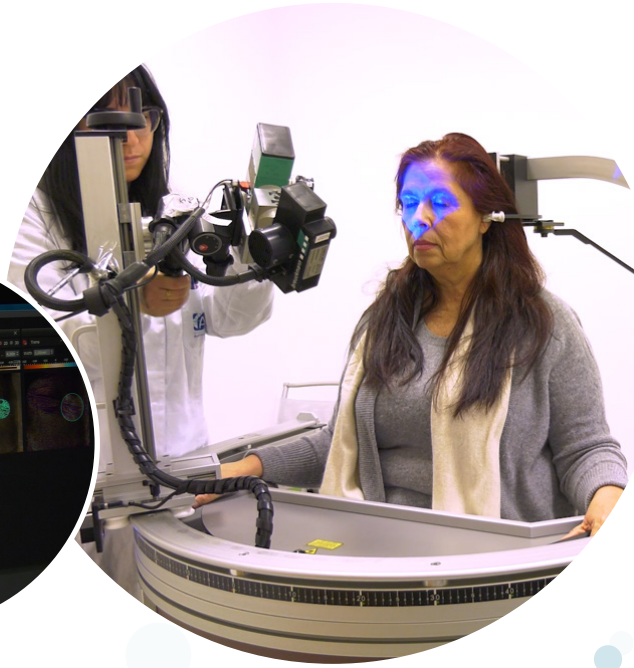
- **Medical and technical assessments** of ethical clearance also for external studies

- **Assessment by an indipendent Ethical commette.**

- **Patients recruitment for clinical investigations** of medical devices and IVD.

- **Pediatric expertises** for cosmetic products intended for childrens and babies use.





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CONSULTING, REGULATORY ASSISTANCE AND EDUCATION

COSMETIC

• **Cosmetic Product Safety Report** according to Regulation (CE) 1223/2009, with signature of a European Registered Toxicologist (ERT).

• **PIF - Product Information File** for cosmetics according to Regulation (CE) 1223/2009.

• **Cosmetic Product Notification** on the web portal CPNP.

• **Formulation design and development** of cosmetic finished products.

• **Development of extraction methods for botanicals.**

• **R&D projects** and support for experimental patents.

• **Assistance for cosmetic labelling ,** according to Regulation (CE) 1223/2009, and environmental labelling.

• **Assistance for new cosmetic plants** and laboratories start-up.

• **Safety Assessment** for ingredients and raw materials.

• **INCI assignment** for new raw materials, MSDS writing.

• **Scientific marketing and communication.**

• **Validation of methods and procedures** for cleaning and sanitization of premises, equipment and plants.

• **Technical education** (toxicology, microbiology, cosmetic testing, regulatory, ISO 22716, design) online and on site (Abich Academy).

• **Customized education** and training on the companies' site.

MEDICAL DEVICES

• **Assistance in the management** of changes from Directive CEE 93/42 (MDD) to Regulation (UE) 2017/ 745(MDR).

• **Support to manufacturers** for the feasability of new medical devices according to MDR.

• **Toxicological and Pharmacokinetic evaluations (ADME)** on bibliographic data with the signature of a European Registered Toxicologist (ERT).

• **Assistance as Person Responsible for the Regulatory Compliance (PRRC)** ex art. 15 MDR.

• **Biological Evaluation Plan** with a chemical and biological testing strategy and Biological Evaluation. Report (BEP and BER) according to ISO 10993-1 .

• **Technical file according to annex II MDR.**

• **Risk assessment** according to ISO 14971.

• **GSPR Table redaction.**

• **Clinical data Evaluation Plan and Report (CEP e CER).**

• **Design and assistance** as a CRO in post-marketing and pre-marketing clinical studies.

• **Assistance in registration** in the EUDAMED data bank for medical devices manufacturers and for products.

• **Assistance in medical devices** labelling according to ISO 15223, ISO 20417 (ex ISO 1041).

• **Support and consulting** for post marketing surveillance (PMS, PMCF e PSUR).

• **Design and R&D for topical products;** manufacturing of pilot batches.

• **Customized regulatory consultancy.**

• **Validation of sterilisation methods.**

• **Technical training and education** (product files, ISO 13485, sterilization, classification, MDR compliance etc) online and on site (Abich Academy).

• **Customized training at the manufacturer's site.**

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CONSULTING, REGULATORY ASSISTANCE AND EDUCATION

MEDICAL-SURGICAL AIDS (PMC) AND BIOCIDES

- **Assistance in the design of safety and efficacy studies.**
- **Technical data sheets and MSDS writing.**
- **Labelling.**
- **Assistance in the notification** to Ministero della Salute and new products filing.

ABICH ACADEMY

Technical and strategical courses for cosmetic, biomedical, textiles and chemical companies.
Webinar and on site training (in Milan, Vimodrone)

- **PIF and CPSR Reg. (CE)1223/2009.**
- **Technical files for MD.**
- **MDR Regulation (UE) 2017/ 745 and MDD Directive CEE 93/42.**
- **Microbiology.**
- **Stability.**
- **In vitro and pre-clinical tests.**
- **Assays on human volunteers.**
- **Clinical investigations for MD.**
- **Good Manufacturing Practices (ISO 22716, ISO 13485).**
- **Risk assessment.**
- **Design of topical products.**
- **Customized training at the client's sites.**

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