MEDICAL DEVICES
Sinerga is a uniqueness in the skincare industry: a multitasking team of experts that combines technical expertise, industrial experience and innovative approach able to offer a complete range of solutions:

1. **R&D and Innovation**
   Research and Development Laboratory studies innovative formulations for finished cosmetic products. Beside that it provides systematic trials on new raw materials in order to deeply evaluate and understand their cosmetic applications. It has been judged by MURST (Minister of University and of Scientific and Technological Research) as highly qualified and therefore enrolled in the National Register of Research laboratories.

2. **Dermocosmetic Raw Materials**
   Sinerga offers a complete range of personal care specialities, most of them of natural origin, deriving from vegetables. Our ingredients are characterized by proved safety, efficacy and excellent “skin compliance”. Product range: Surfactants, Emulsifiers, Preservatives, Microbic Inhibitors, Active Ingredients, Functional Ingredients.

3. **Contract manufacturing**
   A 7,000 m² industrial site equipped with cutting-edge facilities able to meet any requirements, it can handle both pilot or half scale production, and manage daily production of several tons of finished products. Sinerga technical-productive area has obtained the most prestigious Certifications.
   Daily production capacity: 30 tons of semi-processed products
   Daily packaging rate: 125,000 articles.
   Product range: Skincare, Dermocosmetics, Medical Devices class I and II.
Clinical dermatology practice has expanded to include the use of many procedures and devices for cosmetic purposes.

The need for something ancillary and complementary to pharmaceuticals has driven the development of cosmetic solutions that could concur to alleviate or treat the consequences of a disease.

This is a consequence of not only the rising interest in aesthetic medicine but also the economic pressures on the practitioner participating in managed care plans, as well as increasing regulation and requirements of office practice.

Trend to self-cure with less invasive products or medical devices, that cause less adverse events and alleviate chronic symptoms or maintain the results of a previous therapy.
According to Directive 93/42/EEC, a medical device is defined as:

- An article which is intended to be used for a medical purpose, without achievement the use of drugs as its principal intended action in or on the human body by pharmacological, immunological or metabolic means.

- A finished product regardless of whether it is intended to be used alone or in combination.

- An instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body.

The classification rules are based on different criteria such as:

- The duration of contact with the patient
- The degree of invasiveness and the part of the body affected by the use of the device


The two major factors in determining the class of a medical device are:

- Intended purpose
- Destination of use

Classes are established in accordance with MEDDEV 2. 4/1 Rev. 9 June 2010:

- Class I: LOW RISK
- Class IIa: LOW/MEDIUM RISK
- Class IIb: MEDIUM/HIGH RISK
- Class III: HIGH RISK
Sinerga Research Centre manages a Medical Device throughout all the phases: the project, the collection of technical, clinical and toxicological data and the final marking.

- Sinerga manages Medical Devices in classes I, II A, II B that means for topic use such as dermatological, buccal and gynecological products.
- A synergic and complementary team of formulators, dermatologists, pharmacologists and medical specialists collaborates effectively in the management of the full service project.
- Sinerga releases the marked finished Medical Devices either by transferring its license or cover it by OBL contract together with the business partner.

ISO 13485 certification assess the ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements.
MAIN APPLICATION AREAS

MEDICAL DEVICES

ORAL CARE

GYNECOLOGY

FEET & HAND CARE

HAIR CARE

PROCTOLOGY

DERMATOLOGY
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<tr>
<th><strong>GYNECOLOGY</strong></th>
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<th><strong>DERMATOLOGY</strong></th>
<th><strong>HAIR CARE</strong></th>
<th><strong>ORAL CARE</strong></th>
<th><strong>OTHERS</strong></th>
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<tbody>
<tr>
<td>Intimate detergent</td>
<td>Fissures</td>
<td>Acne</td>
<td>Anti Lice</td>
<td>Whitening</td>
<td>Wound healing</td>
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<td>Lubricant detergent</td>
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<td>Rosacea</td>
<td>Anti dandruff</td>
<td>Gengival Gel</td>
<td>Liquid plaster</td>
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<tr>
<td>Mycoses - Candida</td>
<td>Hemorrhoids</td>
<td>Atopy</td>
<td>Anti-seborrhea</td>
<td>Mounthwash</td>
<td>Herpes labiale</td>
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<td>Herpes zoster</td>
<td></td>
<td>Hyperchromias</td>
<td>Hair loss</td>
<td>Toothpaste</td>
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<td>Aphtha</td>
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<td>Dry mucosa</td>
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<td>Itch</td>
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**HOW WE WORK**

**PRODUCT BRIEF**

1. **Product Development and formulating**
2. **ICH Compatibility**
3. **Efficacy and toxicology test**
4. **Medical Device Marking**
5. **Industrial transfer and scale up**
6. **Manufacturing according ISO13485**

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