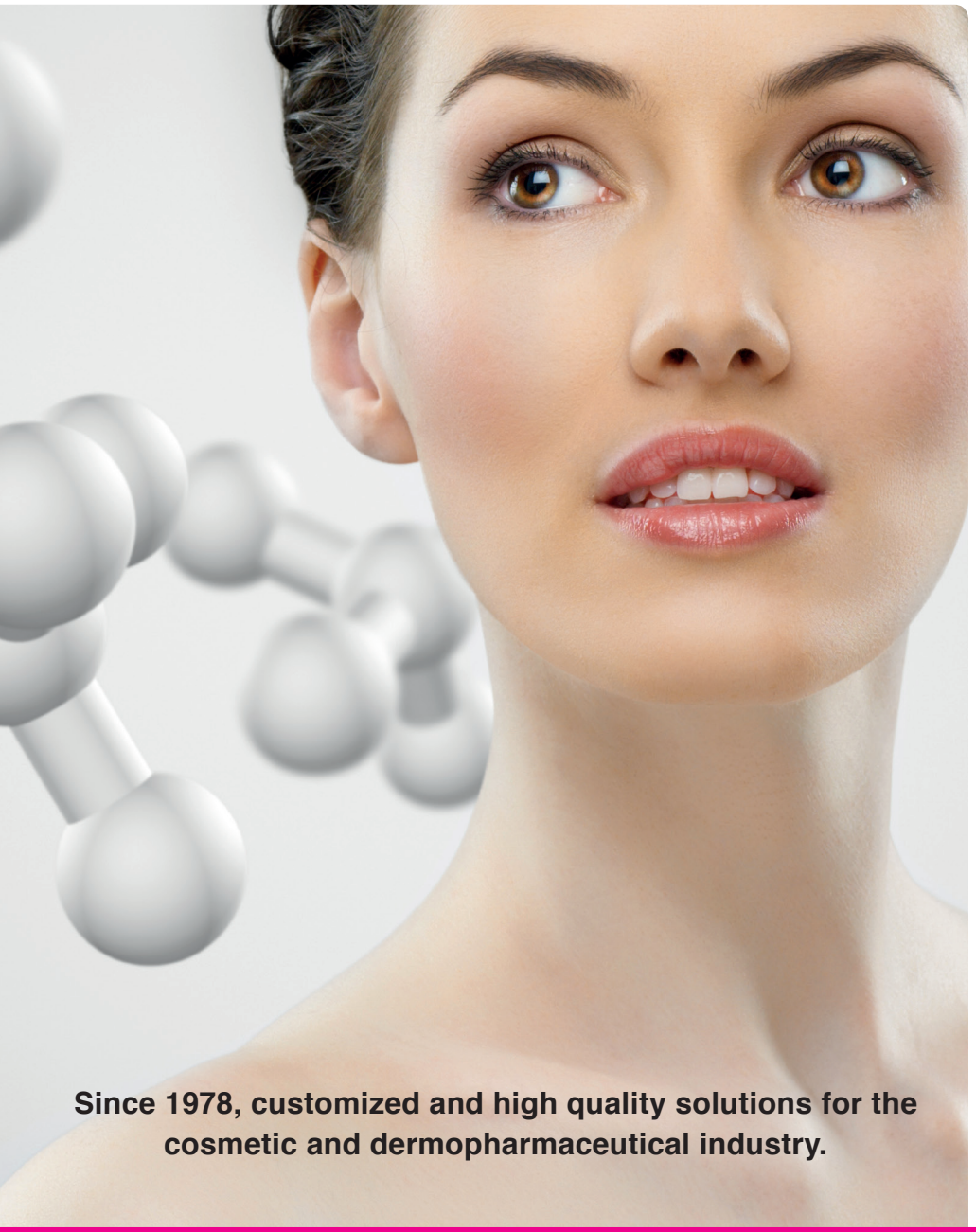
MEDICAL DEVICES

Sinerga
SKIN EVOLUTION

SINERGA



Since 1978, customized and high quality solutions for the cosmetic and dermopharmaceutical industry.

COMPANY PROFILE

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.

RAISE OF MEDICAL DEVICES

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** partecipating 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.

MEDICAL DEVICES: WHY?

- High quality care
- Improvement of people quality of life
- Demand for high technological products
- Diagnosis, prevention, monitoring and treatment
- Either noninvasive or minimally invasive

MEDICAL DEVICES

DEFINITION

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.**

CLASSIFICATION

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

Rules are defined in chapter III of Annex IX of Directive 93/42/EEC as emended by Directive 2007/47/CE

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

- Intented 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

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SINERGA MEDICAL DEVICES DEVELOPMENT

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.

UNI EN ISO 13485:2004

QUALITY MANAGEMENT SYSTEM CERTIFICATION

CERTIQUALITY
ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ

CERTIFICATO N.
CERTIFICATE No 17572

SINERGA SPA

IT - 20154 MILANO (MI) - VIA A. BERTANI 6

IT - 20016 PERO (MI) - VIA PITAGORA 3
IT - 21050 GORLA MAGGIORE (VA) - VIA DELLA PACCIARINA 67

UNI EN ISO 13485:2004

EA 12

Produzione e confezionamento per terzi di dispositivi medici in forma liquida, semisolida, gel e crema.
Studi e ricerche formulative di dispositivi medici per aziende terze.
Third-party manufacturing and packaging of medical devices in liquid, semisolid, gel and cream state.
Custom formulations service of medical devices.

05/06/2012
05/06/2012
04/06/2015

CERTIQUALITY S.r.l. - IL DIRETTORE GENERALE

ACCREDIA

CISQ

IQNet

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

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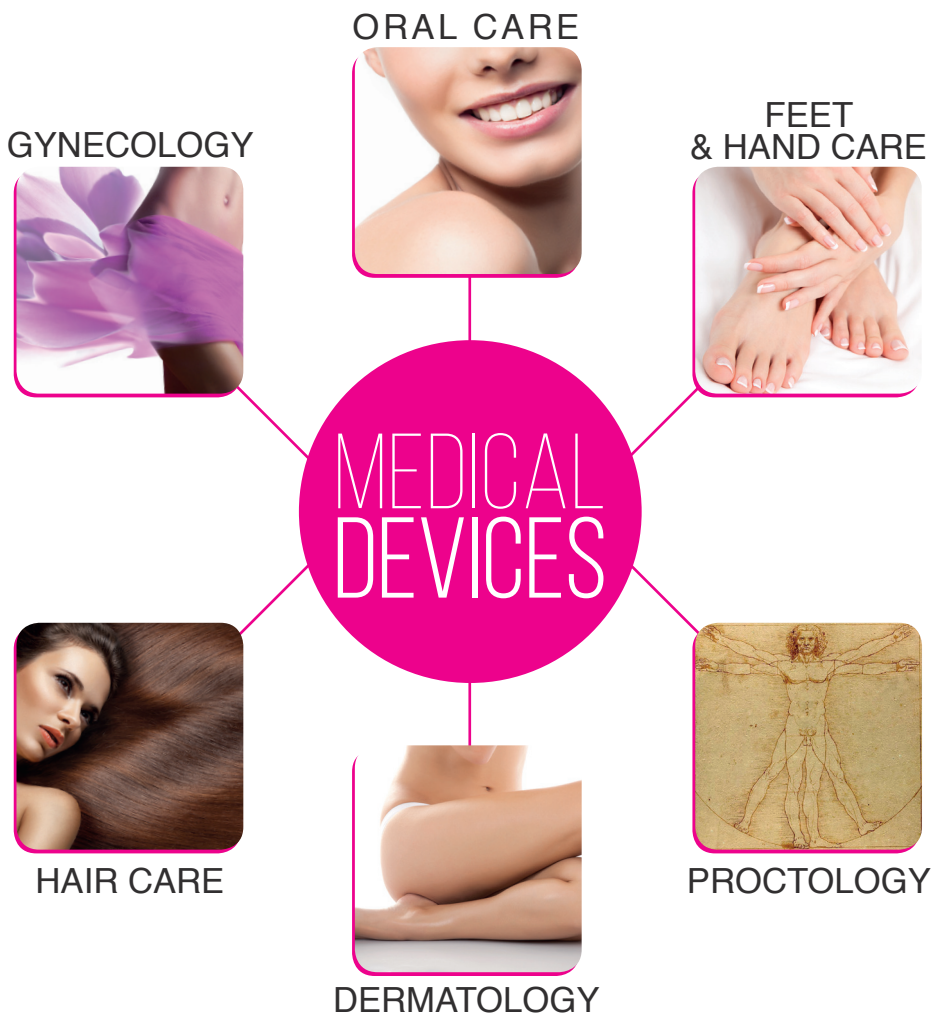
MAIN APPLICATION AREAS



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EXPERTISES

GYNECOLOGY	PROCTOLOGY	DERMATOLOGY
Intimate detergent	Fissures	Acne
Lubricant detergent	Hemorrhoids	Rosacea
Mycoses - Candida		Atopy
Herpes zoster		Hyperchromias
		Anti-age
		Cellulite
		Anti-seborrhea
		Teleangectasies
		Radiodermatitis
		Herpes zoster
		Sun care
		Hyperhidrosis

HAIR CARE	ORAL CARE	OTHERS
Anti Lice	Whitening	Wound healing
Anti dandruff	Gengival Gel	Liquid plaster
Anti-seborrhea	Mounthwash	Herpes labiale
Hair loss	Toothpaste	Muscle Pain
FEET CARE	Aphtha	Keloids
Fissures	Dry mucosa	Psoriasis
Callus		Itch
Mycoses - Athlet's foot		Skin in chemioterapy
Vesicles		

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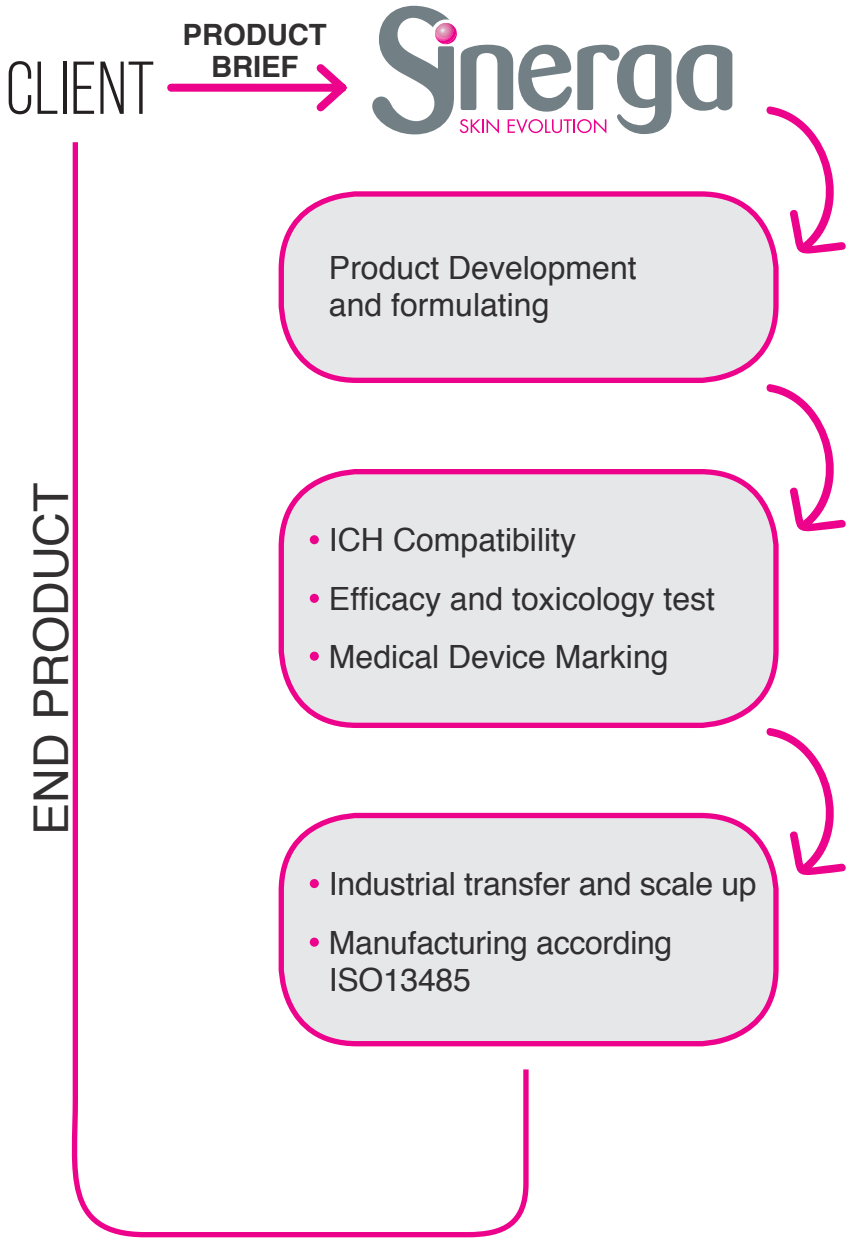
HOW WE WORK



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