

## Regulatory, scientific and medical information

Why Stratamed can be used on  
non epithelialized wounds and  
compromised skin





## Stratamed® – the regulatory background

Stratamed is an advanced polymer formulation, used for the prevention and treatment of abnormal scars. It meets all conformity assessment requirements to be used on non epithelialized wounds and compromised skin.

### Registration and classification of Stratamed

Stratamed has been reviewed for the indications stated and is approved for sale as a Class IIa medical device CE 1254. "1254" represents the registration number of the notified body, QS Zurich, which issued the certificate.

The notified body is an organisation that is registered with and authorised by the regulatory authority ("Swissmedic" for swiss manufacturers) to perform the conformity assessments for medical devices and to issue CE certificates for products of Class IIa and above.

Class I products do not carry a 4 digit number with their CE mark, as the declaration of conformity is carried out by the manufacturers themselves (self-assessment).

### Conformity assessment process

The product claims, the directions for use, and the indications determine the class of a medical device. As it can be used on open wounds and on compromised skin and is principally intended to manage the micro-environment of a wound, Stratamed has been registered as a Class IIa device in the European Community.

Stratamed has then been assessed for conformity against the European Medical Device Directive 93/42/EEC (according to its class). The manufacturer, Stratapharma AG, had to meet all requirements of the directive.

A technical file of approximately 1000 pages was prepared by Stratapharma AG to demonstrate conformity to the comprehensive and strict requirements of the Directive 93/42/EEC.

The technical file has been assessed by the notified body for conformity, which concluded that all requirements have been successfully fulfilled. Then the appropriate CE certificate has been issued, which allows the "CE 1254" mark to be attached to the product.

### Most critically, the following have been assessed and verified as part of the conformity process:

1. All product claims have been proven and verified in accordance with the directive.
2. The safety profile and biocompatibility of Stratamed have been demonstrated for use on open (non epithelialized) wounds and compromised skin.  
  
Stratamed contains components of strict medical grade quality that have been tested and which meet the strict requirements for
  - Toxicology
  - Skin sensitization
  - Subcutaneous irritation
3. Stratamed is manufactured and released under **GMP conditions**.
4. Stratapharma's quality management system (ISO 13485) for the manufacture of medical devices has been assessed and certified.

**Conclusion:** Stratamed, a non sterile silicone gel formulation for use on **open (non epithelialized) wounds** and **compromised skin** has fulfilled all conformity requirements as a Class IIa medical device, and has been approved for sale.

## Stratamed – the scientific background

**Silicon (Si) is a semimetal and the second most abundant element in the earth's crust (25.7%) and is a major component of many minerals (silicates).**

- Silicones are industrially produced compounds derived from the element silicon.
- Silicones are high performance oligomers or polymers that can take a variety of physical forms, ranging from solids to water-thin liquids and semi-viscous pastes, greases and oils.
- Silicones have long been recognised by the medical world as efficient, versatile and biocompatible materials for use in medical care, dental care, infant care, pharmaceuticals, treatment of wounds and prosthetics.
- Medical applications/products with silicone satisfy the highest quality standards demanded by health care professionals. They feature:
  - resistance to bacteria
  - gentle adhesion
  - flexibility and moldability
  - strength and durability
  - superior biocompatibility
- Silicones do not react with other materials and do not irritate the body. When used externally or intravenously, they do not generate unwelcome byproducts or trigger allergic reactions.



### Silicones for medical application – the science behind the products<sup>1</sup>

Silicone features	Benefits
Inert	<ul style="list-style-type: none"> <li>– Does not harbour or proliferate bacterial growth</li> <li>– Will not stain or corrode other materials</li> </ul>
No pH value	<ul style="list-style-type: none"> <li>– Does not affect the protective acid mantle of the skin</li> </ul>
Strong chemical bonds	<ul style="list-style-type: none"> <li>– Not susceptible to oxidation</li> <li>– Not susceptible to thermal degradation</li> </ul>
High molecular weight	<ul style="list-style-type: none"> <li>– Not absorbed through the skin</li> <li>– Not absorbed into the human gastrointestinal tract</li> <li>– Excreted without modification</li> </ul>
Low chemical reactivity	<ul style="list-style-type: none"> <li>– Superior biocompatibility with human tissue and other body fluids</li> </ul>
Low surface energy	
Hydrophobicity	

## Stratamed – the medical background

Stratamed is a breakthrough treatment that can be used on non epithelialized wounds and compromised skin, which allows prevention of abnormal scarring to begin earlier than ever before

### Reduction of inflammatory response

Stratamed forms a flexible, protective sheet that weakly bonds to the injured skin and protects it from chemical and microbial invasion. Stratamed consists of inert silicone polymers with no measurable pH value, which do not affect the protective acid mantle of the skin and do not react with the newly forming epithelial tissue.

**This leads to a reduction in the inflammatory response, an effective healing of the wound and therefore enhances therapeutic results.<sup>2</sup>**

### Faster re-epithelialization of the wound bed

Stratamed's protective and hydrophobic silicone film has a semi-occlusive effect and therefore improves the tissue hydration of the injured skin area. It does not adhere strongly to the newly formed granulating tissue, which allows a faster migration of keratinocytes across the wound bed.

**This leads to a faster re-epithelialisation<sup>2</sup>, dramatically decreases the incidence of abnormal scarring<sup>3</sup> and gives patients a faster recovery time<sup>2</sup>.**

### Abnormal scar prevention

Stratamed restores the barrier function of the stratum corneum, reduces Trans-Epidermal Water Loss (TEWL) and stops dehydration of the skin.<sup>4</sup>

**This leads to a normalized level of collagen production, resulting in a normal mature scar.<sup>4</sup>**

Stratamed modulates the level of basic fibroblastic growth factors (bFGF).<sup>5</sup>

**This prevents the formation of hypertrophic scar tissue.<sup>5</sup>**



**Stratamed can be used immediately after surgical procedures, trauma, skin resurfacing, burns\* and radiation therapy.**

- Allows prevention of abnormal scarring to begin earlier than ever before
- Faster wound healing<sup>2</sup>
- Faster recovery time

**Stratamed is a simple addition to existing wound care protocols with no changes required. It can be used with or without secondary protective dressing.**

- Simple, easy, safe and convenient to use
- Patients can continue treatment at home
- Enhances therapeutic results<sup>2</sup>