

PRODUCT DATA SHEET

STELLA[®] Gauze Dressings, 8-ply, sterile

REF: 35001, 35867, 35866, 35801, 35804, 35807, 35002,
35003, 35835, 35905, 35965, 35932, 35968, 35969,
35004, 35864, 35005, 35845, 35827, 35935, 35937,
35813

January 2009

Translation: MI / Km

1. Composition of the product

Stella^(R) X-ray Detectable Gauze Dressings, sterile, consist of 17-thread absorbent cotton gauze EN 14079.

This product data sheet covers the following items:

REF 35001	Stella [®] Gauze Dressings, 8-ply, sterile	5 x 5 cm
REF 35867	Stella [®] Gauze Dressings, 8-ply, sterile	5 x 5 cm
REF 35866	Stella [®] Gauze Dressings, 8-ply, sterile	5 x 5 cm
REF 35801	Stella [®] Gauze Dressings, 8-ply, sterile	5 x 5 cm
REF 35804	Stella [®] Gauze Dressings, 8-ply, sterile	5 x 5 cm
REF 35807	Stella [®] Gauze Dressings, 8-ply, sterile	5 x 5 cm
REF 35002	Stella [®] Gauze Dressings, 8-ply, sterile	7,5 x 5 cm
REF 35003	Stella [®] Gauze Dressings, 8-ply, sterile	7,5 x 7,5 cm
REF 35835	Stella [®] Gauze Dressings, 8-ply, sterile	7,5 x 7,5 cm
REF 35905	Stella [®] Gauze Dressings, 8-ply, sterile	7,5 x 7,5 cm
REF 35965	Stella [®] Gauze Dressings, 8-ply, sterile	7,5 x 7,5 cm
REF 35932	Stella [®] Gauze Dressings, 8-ply, sterile	7,5 x 7,5 cm
REF 35968	Stella [®] Gauze Dressings, 8-ply, sterile	7,5 x 7,5 cm
REF 35969	Stella [®] Gauze Dressings, 8-ply, sterile	7,5 x 7,5 cm
REF 35004	Stella [®] Gauze Dressings, 8-ply, sterile	7,5 x 10 cm
REF 35864	Stella [®] Gauze Dressings, 8-ply, sterile	7,5 x 10 cm
REF 35005	Stella [®] Gauze Dressings, 8-ply, sterile	10 x 10 cm
REF 35845	Stella [®] Gauze Dressings, 8-ply, sterile	10 x 10 cm
REF 35827	Stella [®] Gauze Dressings, 8-ply, sterile	10 x 10 cm
REF 35935	Stella [®] Gauze Dressings, 8-ply, sterile	10 x 10 cm
REF 35937	Stella [®] Gauze Dressings, 8-ply, sterile	10 x 10 cm
REF 35813	Stella [®] Gauze Dressings, 8-ply, sterile	10 x 10 cm

2. Packaging, structure and composition

2.1 Unit container

- a peel pouch having:
 - a cellulose top
 - a bottom of transparent polyamide/polyethylene film

2.2 Shelf container

- a cellulose folding box

2.3 Transit container

- a corrugated cardboard case (cellulose)

3. Manufacture

Stella® Gauze Dressings are produced to specification under hygienic conditions and presented in sets packed as described in their respective packaging specifications. They are sterilized by ethylene oxide in compliance with DIN EN 550.

4. Description

White to pale yellow 8-/ or 12-ply gauze dressings folded in such a way that no cut edges are exposed and layers do not telescope. Folded “the American way” the gauze dressings are available in several sizes

5. Properties

Stella® Gauze Dressings, sterile are soft and highly absorbent. With the cut edges folded inside, there are no loose threads on the product..

They are intended for single use only and must not be re-sterilized

Stella® Gauze Dressings, sterile, are sterile as long as the packaging remains unopened and undamaged.

6. Intended purpose/use

The above sterile gauze dressings are intended for cleaning and covering wounds.

7. Medical device classification

As non-invasive medical devices used as a mechanical barrier, for compression or for the absorption of exudates, *Stella® Gauze Dressings, sterile*, are in Class Is according to Rule 4, Annex IX of the Council Directive 93/42/EEC concerning medical devices

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

Cotton i.e. absorbent cotton gauze is described in monographs in national and international pharmacopoeia. Absorbent cotton gauze is known to be pharmacotoxicologically harmless and indifferent. Because of its excellent biocompatibility cotton is used especially in the textile industry.

The starting material utilized to produce *Stella® Gauze Dressings, sterile* is safe providing the product is used correctly and for the purposes intended.

To date this company has received no notification of incidents involving this Lohmann & Rauscher product, neither has there been a need for a recall of *Stella® Gauze Dressings, sterile* for reasons of quality.

The purpose of this documentation and of the statements made therein is to show that there is no risk involved in the use of *Stella® Gauze Dressings, sterile* and that - as it says in the Essential Requirements of the Council Directive 93/42/EEC concerning medical devices - *Stella® Gauze Dressings, sterile* "are designed, manufactured and packaged in such a way that they will not compromise the clinical condition or the safety of patients, or the safety and health of users or other persons when used under the conditions and for the purposes intended".

9. Stability

Stored appropriately, *Stella® Gauze Dressings, sterile* have a shelf life of 5 years.

10. Disposal

Incineration or landfill disposal of the product will generate CO₂ and H₂O, of the packaging materials CO₂, H₂O and traces of nitrous gases.

The user is advised to observe current local legislation, norms and guidelines, regulating the disposal of medical refuse.

Lohmann & Rauscher International GmbH & Co. KG
D-56579 Rengsdorf
signed by
Dr. Martin Abel
(Medical & Regulatory Affairs)