1. Composition of the product:

The construction i.e. composition of Sentinex® Surgical Gowns SMMS, sterile, standard and special, is as follows:

- **Gown material**: polypropylene SMMS
- **Cuffs, knitted**: polyester
- **Hook & loop fastener**: polypropylene, polyamide
- **Transfer card**: cardboard
- **Overwrap**: cellulose
- **Towels**: white cellulose tissue

Sleeves and front of the surgical gown “special” are reinforced. These reinforcements consist of an adhesive-laminated composite material of a polypropylene non-woven material and a polyethylene film.

This product data sheet covers the following items:

- REF 19340 Sentinex® Standard Surgical Gown SMMS, sterile, 120 cm - sterile wrapping
- REF 19341 Sentinex® Standard Surgical Gown SMMS, sterile, 130 cm - sterile wrapping
- REF 19342 Sentinex® Standard Surgical Gown SMMS, sterile, 150 cm - sterile wrapping
- REF 19344 Sentinex® Standard Surgical Gown SMMS, sterile, 150 cm, large - sterile wrapping
- REF 19343 Sentinex® Standard Surgical Gown SMMS, sterile, 170 cm - sterile wrapping
- REF 19360 Sentinex® Standard Surgical Gown SMMS, sterile, 120 cm
- REF 19361 Sentinex® Standard Surgical Gown SMMS, sterile, 130 cm
- REF 19362 Sentinex® Standard Surgical Gown SMMS, sterile, 150 cm
- REF 19364 Sentinex® Standard Surgical Gown SMMS, sterile, 150 cm, large
- REF 19363 Sentinex® Standard Surgical Gown SMMS, sterile, 170 cm
- REF 19350 Sentinex® Special Surgical Gown SMMS, sterile, 120 cm - sterile wrapping
- REF 19351 Sentinex® Special Surgical Gown SMMS, sterile, 130 cm - sterile wrapping
- REF 19352 Sentinex® Special Surgical Gown SMMS, sterile, 150 cm - sterile wrapping
- REF 19354 Sentinex® Special Surgical Gown SMMS, sterile, 150 cm, large - sterile wrapping
- REF 19353 Sentinex® Special Surgical Gown SMMS, sterile, 170 cm - sterile wrapping
REF 19370 Sentinex® Special Surgical Gown SMMS, sterile, 120 cm
REF 19371 Sentinex® Special Surgical Gown SMMS, sterile, 130 cm
REF 19372 Sentinex® Special Surgical Gown SMMS, sterile, 150 cm
REF 19374 Sentinex® Special Surgical Gown SMMS, sterile, 150 cm, large
REF 19373 Sentinex® Special Surgical Gown SMMS, sterile, 170 cm

2. **Packaging, structure and composition**

2.1. Unit container
- see 2.2.

2.2. Shelf container
- a deep draw bag of cellulose, polyamide and polyethylene

2.3. Transit container
- a polyethylene bag
- a corrugated cardboard case

3. **Manufacture**

Sentinex® Surgical Gowns SMMS, sterile, standard and special, are manufactured to specification under hygienic conditions and wrapped as described in their respective packaging specifications. They are sterilized by ethylene oxide in compliance with DIN EN 550.

4. **Description**

Turquoise-coloured disposable surgical gowns with a white hook and loop nape closure, white binding at the neck and extra long white knitted cuffs. Two binding tapes are welded to the waist. The gowns are presented individually wrapped. Those presented with extra sterile wrapping (REF 19340 – 19344, and REF 19350 – 19354) include two small white towels each.

5. **Properties**

Sentinex® Surgical Gowns SMMS, sterile, standard and special, are fluid-repellent disposable surgical gowns. They are free of latex, abrasion resistant and lint-free. The Sentinex® Surgical Gown SMMS sterile “special” has fluid-repellent reinforcements on the inside of the sleeves and inside the front part. The gowns’ special cut allows sterile conditions also at the back. The gowns are folded ready for use.
6. **Intended purpose/use**

Sentinex® Surgical Gowns SMMS, sterile, standard and special, are single-use gowns to be worn during surgical procedures.

7. **Medical device classification**

Used as protective apparel during surgical procedures Sentinex® Surgical Gowns SMMS, sterile, standard and special, are in Class Ia according to Rule 1, Annex IX of the Council Directive 93/42/EEC concerning medical devices.

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

Sentinex® Surgical Gowns SMMS, sterile, standard and special, will be in direct contact with healthy and intact skin only.

Based on the clinical evaluation and risk analysis carried out, the medico-pharmacological safety of Sentinex® Surgical Gowns SMMS, sterile, standard and special, is guaranteed providing they are 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 product recall 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 Sentinex® Surgical Gowns SMMS, sterile, standard and special, and that - as it says in the Essential Requirements of the Council Directive 93/42/EEC concerning medical devices - Sentinex® Surgical Gowns SMMS, sterile, standard and special "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 Sentinex® Surgical Gowns SMMS, sterile, standard and special, have a shelf life of 5 years.
10. Disposal

Incineration or landfill disposal of Sentinex ® Surgical Gowns SMMS, sterile, standard and special will generate of both product and packaging CO₂, H₂O and traces of nitrous gases.

The user is advised to observe current 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)