

Zelletten® Cellulose swabs off the roll

REF 13349, 13356, 13353, 13357

July 2019

1. Composition of the product

Zelletten® Cellulose Swabs of the roll consist of:

- bleached, 12-sheet cellulose wadding

This product data sheet covers the following items:

REF	Size	Roll	packaging
13349	5 x 4 cm	1 Roll á 300 Pcs.	transparent dispenser
13356	5 x 4 cm	2 Rolls á 500 Pcs.	in a bag
13353	5 x 4 cm	1 Roll á 500 pcs.	in a bag pathogen reduced
13357	5 x 4 cm	20 Rolls á 500 pcs	in a bag individual article

2. Packaging, structure and composition

2.1 Unit container

see 2.2

2.2 Shelf container

REF 13349

transparent dispenser made of polysterol

folding box, made of cellulose

Packaging units see product table above

REF 13353, 13356, 13357

bag made of polyethylene (REF 13356 with drawcord-clip)

Packaging units see product table above

2.3 Transit container

1 corrugated cardboard box (cellulose)

REF	packings	units
13349	20	20 folding boxes
13356	12	12 bags = 24 rolls
13353	20	20 bags
13357	1	20 bags

3. Manufacture

Zelletten® Cellulose Swabs of the roll are produced according to specification under hygienic conditions and wrapped as described in the relevant packaging specification. Zelletten with REF 13353 are pathogen reduced during the manufacturing process.

4. Description

White, smooth, odourless cellulose swabs (the micro-count reduced swabs can be slightly yellowish) the cellulose is bleached chlorine free.

5. Properties

Zelletten® Cellulose Swabs of the roll consists of chlorine-free bleached bandage pulp.

6. Intended purpose

Zelletten® Cellulose Swabs are used for skin cleansing in the field of nursing care and treatment.

7. Medical device classification

Zelletten® Cellulose Swabs are medical devices of class I according to rule 1. (Council Directive 93/42/EEC concerning medical devices, Annex IX)

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

The starting materials used in the manufacture of Zelletten® Cellulose Swabs of the roll are safe if the product is used appropriately.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device Zelletten® Cellulose Swabs and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

9. Stability

Stored appropriately Zelletten® Cellulose Swabs off the roll have a shelf life of 5 years.

10. Disposal

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

Packaging materials must also be disposed of in compliance with applicable national requirements.

Lohmann & Rauscher International GmbH & Co. KG
D-56579 Rengsdorf
signed by
Dr. Klemens Schulz
Executive Board/ Chief Portfolio Officer