ES Kompressen (sterile) in folding box/dispenser

MEDICAL DEVICE

General Product Description/Intended Purpose

White gauze swabs are non-active devices, which are made of 100 % cotton. They are available with different numbers of threads per cm2, in different sizes and with different numbers of layers. Swabs can be unfolded to get bigger sizes.

Non-invasive use
Single-use, sterile gauze swabs are used by laypersons and healthcare professionals on humans on intact skin for up to long-term and on injured skin for up to short-term. They are used as a primary or secondary dressing for wounds, for cleansing of skin, for absorption of body fluids, as a mechanical barrier, and as carrier material of externals. Gauze swabs are fixed on the patient by fixation material and can be used in the context of compression therapy.

Invasive use
Single-use, sterile gauze swabs are used by laypersons and healthcare professionals on natural body cavities, injured skin and mucosal membranes on humans for up to short-term. They are used as a primary or secondary dressing for wounds, for cleansing of skin, for absorption of body fluids, as a mechanical barrier, and as carrier material of externals. Gauze swabs are fixed on the patient by fixation material.

Surgically invasive use
Single-use, sterile gauze swabs are used by healthcare professionals on breached or compromised surfaces and underlying tissue on humans for up to short-term. They are used for the absorption of body fluids in the context of minor surgeries.
Medical Device class : IIa

Application/Indication

Gauze swabs achieve absorption of body fluids (e.g. exudate, blood) due to use of light, wide-meshed cotton fabric (gauze), which makes the device also suitable as a carrier material of externals e.g. disinfectants, ointments and/or as a mechanical barrier. The device is fixed on the patient by bandages, tapes or other fixation materials as a primary and/or secondary dressing for wounds..

Regardless of the quantity of plies, ES Swabs can be unfolded without interfering fringe threads until 4 layers remain. The device is fixed on the patient by bandages, tapes or other fixation materials as a primary and/or secondary dressing for wounds. The device can be used:

- as a primary and secondary dressing for wounds
- for cleansing of the skin
- for absorption of body fluids (e.g. exudate or blood)
- as a mechanical barrier
- as carrier material of externals (e.g. disinfection, ointments)

The device can be used in the context of compression therapy and/or minor surgeries.

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Catalogue Numbers
Folding box

REF	name	size [cm]	gauze type	number of ply	pieces per pouch	pouch per folding box
EO sterilized acc. to EN ISO 11135						
4014359	ES Kompressen (sterile)	10 x 10	17 threads	12	5	10
4017359	ES Kompressen (sterile)	10 x 10	17 threads	12	2	25
4017459	ES Kompressen (sterile)	10 x 20	17 threads	8	2	25
4018049	ES Kompressen (sterile)	7.5 x 7.5	17 threads	16	5	20
4755039	ES Kompressen (sterile)	7.5 x 7.5	17 threads	12	5	20
4755069	ES Kompressen (sterile)	10 x 10	17 threads	12	5	20
2050100	ES Kompressen (sterile)	10 x 10	17 threads	12	5	10
2050110	ES Kompressen (sterile)	10 x 10	17 threads	12	2	25
2050120	ES Kompressen (sterile)	10 x 20	17 threads	8	2	25
2050130	ES Kompressen (sterile)	7.5 x 7.5	17 threads	16	5	20
2050140	ES Kompressen (sterile)	7.5 x 7.5	17 threads	12	5	20
2050150	ES Kompressen (sterile)	10 x 10	17 threads	12	5	20
2050030	ES Kompressen (sterile)	7.5 x 7.5	17 threads	8	2	10
2050040	ES Kompressen (sterile)	10 x 10	17 threads	8	2	10
4755005	ES Kompressen (sterile)	5x 5	17 threads	12	5	20
4755045	ES Kompressen (sterile)	7.5 x 7.5	17 threads	12	10	10
4755055	ES Kompressen (sterile)	7.5 x 7.5	17 threads	12	20	5
4755085	ES Kompressen (sterile)	10x 10	17 threads	12	20	5
4755095	ES Kompressen (sterile)	10 x 10	17 threads	12	5	20
4755025	ES Kompressen (sterile)	5 x 5	17 threads	12	20	5
4755026	ES Kompressen (sterile)	5 x 5	17 threads	12	20	5
4755075	ES Kompressen (sterile)	10 x 10	17 threads	12	10	10
4755076	ES Kompressen (sterile)	10 x 10	17 threads	12	10	10
Steam sterilized acc. to EN ISO 17665						
4755004	ES Kompressen (sterile)	5 x 5	17 threads	12	5	20
4755014	ES Kompressen (sterile)	5 x 5	17 threads	12	10	10
4755024	ES Kompressen (sterile)	5 x 5	17 threads	12	20	5
4755044	ES Kompressen (sterile)	7.5 x 7.5	17 threads	12	10	10
4755054	ES Kompressen (sterile)	7.5 x 7.5	17 threads	12	20	5
4755074	ES Kompressen (sterile)	10 x 10	17 threads	12	10	10
4755084	ES Kompressen (sterile)	10 x 10	17 threads	12	20	5
4755094	ES Kompressen (sterile)	10 x 20	17 threads	12	5	20

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Dispenser

REF	name	size [cm]	gauze type	number of ply	pieces per pouch	pouch per dispenser
Steam sterilized acc. to EN ISO 17665						
4000304	ES Kompressen (sterile)	10 x 10	17 threads	8	10	10
4017984	ES Kompressen (sterile)	10 x 10	17 threads	16	10	10
4018004	ES Kompressen (sterile)	5 x 5	17 threads	16	10	10
4018014	ES Kompressen (sterile)	5 x 5	17 threads	16	5	20
4018034	ES Kompressen (sterile)	7.5 x 7.5	17 threads	16	10	10
4018074	ES Kompressen (sterile)	9 x 7.5	17 threads	16	5	20
4018154	ES Kompressen (sterile)	10 x 12.5	17 threads	16	2	40
4018194	ES Kompressen (sterile)	18 x 8	17 threads	16	5	20
4018204	ES Kompressen (sterile)	18 x 8	17 threads	16	2	40
EO sterilized acc. to EN ISO 11135						
4018035	ES Kompressen (sterile)	7.5 x 7.5	17 threads	16	10	10
4000305	ES Kompressen (sterile)	10 x 10	17 threads	8	10	10
4000306	ES Kompressen (sterile)	10 x 10	17 threads	8	10	10
4018075	ES Kompressen (sterile)	9 x 7.5	17 threads	16	5	20
4018155	ES Kompressen (sterile)	10 x 12.5	17 threads	16	2	40
4018195	ES Kompressen (sterile)	18 x 8	17 threads	16	5	20
4018205	ES Kompressen (sterile)	18 x 8	17 threads	16	2	40
4019000	ES Kompressen (sterile)	5 x 5	17 threads	8	2	50
4019010	ES Kompressen (sterile)	7.5 x 7.5	17 threads	8	2	50
4019020	ES Kompressen (sterile)	10 x 10	17 threads	8	2	50
4018184	ES Kompressen (sterile)	18 x 8	17 threads	16	10	10
4018185	ES Kompressen (sterile)	18 x 8	17 threads	16	10	10
4017257	ES Kompressen (sterile)	10 x 10	17 threads	8	2	25
4017315	ES Kompressen (sterile)	5 x 5	17 threads	12	2	25
4017337	ES Kompressen (sterile)	7.5 x 7.5	17 threads	12	2	25
4017995	ES Kompressen (sterile)	10 x 10	17 threads	16	2	40
4018025	ES Kompressen (sterile)	5 x 5	17 threads	16	2	40
4018055	ES Kompressen (sterile)	7.5 x 7.5	17 threads	16	2	40
4018095	ES Kompressen (sterile)	10 x 10	17 threads	16	5	20
4004265	ES Kompressen (sterile)	5 x 5	17 threads	12	1	100
4015155	ES Kompressen (sterile)	10 x 10	17 threads	12	1	50
4017215	ES Kompressen (sterile)	5 x 5	17 threads	8	2	25
4017985	ES Kompressen (sterile)	10 x 10	17 threads	16	10	10
4017986	ES Kompressen (sterile)	10 x 10	17 threads	16	10	10
4017235	ES Kompressen (sterile)	7.5 x 7.5	17 threads	8	2	25

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Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings
Not known

Sterile Device
The sterile packaging is in accordance with DIN EN ISO 11607.
Sterilization with ethylenoxide according to DIN EN ISO 11135 or steam according to DIN EN ISO 17665 with validated process.

Instruction	Symbol acc. to EN ISO 15223-1
Do not use if package is damaged	
Do not resterilize	

Single Use Device
Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal
To minimize the risk of potential infection hazards, or environmental pollution, disposable components of ES Swabs should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting
For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Product Performance Characteristics

ES Kompressen, sterile	
Property	**value**
Sinking time	< 10 sec
Number of threads	warp 100 ± 5/100 mm weft 70 ± 4/100 mm
Area weight	≥ 23 g/m2 for 17threads
Tensile strength dry	warp ≥ 50 N/50 mm weft ≥ 30 N/50 mm
Optical brighteners	none
Absorption	4g/g (400%)

Material Characteristics

Gauze
100% chlorine free bleached cotton according EN 14079

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Labelling

Lot-No. with 9-Digit Code
e.g.:

LOT	9	999	XX	XX	X
explanation	[9 = 2019]	[999-000]			
definition	year	serial production order		for internal purposes only	

Date of manufacture

e.g.:	2023 year	04 month	01 day

Use-by Date

e.g.:	2028	04	01
	year	month	day

Shelf Life: 5 years

Medical Device

MD

Unique Device Identifier

UDI

Single Sterile Barrier System

Single sterile barrier system

Date of revision of the text: 2023 – 11 - 10

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