

Medicomp® sterile

General Product Description/Intended Purpose

The products are non-active devices. The swabs are made of a mixture of viscose and polyester fibres. It is free of binding agents and optical brighteners, and permeable to air, available in four plies. Swabs can be unfolded to get bigger sizes. The sterile devices are packed in paper-film-pouches.

Invasive use:

Single-use, sterile swabs are used on humans by lay persons and healthcare professionals for short-term use, for the absorption of body fluids, e.g. exudate or blood, on injured skin, natural body cavities and mucosal membranes also in the context of minor surgeries.

Non-invasive use:

Single-use, sterile swabs are used on humans by lay persons and healthcare professionals as a primary or as a secondary wound dressing, respectively, in combination with ointments and compression material such as a bandage for up to long term use; a new device can be applied indefinitely.

Indication

The device is used for general wound treatment, also in the context of surgical interventions, which includes its use

- as primary dressing for injured skin,
- as initial wound cleansing and cleansing of intact and injured skin,
- as carrier material of externals e.g. disinfection, ointments,
- as secondary dressing for acute wounds and chronic wounds,
- for padding of wounds,
- and for absorption of body fluids.

Furthermore, it can be used as mechanical barrier.

Medical device class

The product is classified as Medical device class IIa according to EU directive 93/42/EEC for medical devices and will be classified after final confirmation of certification as class IIa according to MDR (Regulation 2017/745/EU on Medical Devices).

Reference Numbers

Products available in folding boxes:

REF	name	size [cm]	grammage	number of ply	pieces per pouch	pouches per box
4110494	Medicomp® sterile	7,5 x 7,5	30	4	2	100
4110503	Medicomp® sterile	10 x 10	30	4	2	100
4110514	Medicomp® sterile	5 x 5	30	4	5	40
4110524	Medicomp® sterile	7,5 X 7,5	30	4	5	40
4110533	Medicomp® sterile	10 x 10	30	4	5	40
4110555	Medicomp® sterile	7,5 x 7,5	40	4	2	75
4110563	Medicomp® sterile	10 x 10	40	4	2	75
4110585	Medicomp® sterile	5 x 5	40	4	5	30
4110594	Medicomp® sterile	7,5 x 7,5	40	4	5	30

Medicomp® sterile

REF	name	size [cm]	grammage	number of ply	pieces per pouch	pouches per box
4110603	Medicomp® sterile	10 x 10	40	4	5	30
4110613	Medicomp® sterile	7,5 x 10	40	4	5	30
4110641	Medicomp® sterile	10 x 10	30	4	2	25
4110721	Medicomp® sterile	7,5 x 7,5	30	4	2	25
4110733	Medicomp® sterile	10 x 10	40	4	10	15
4110741	Medicomp® sterile	5 x 5	30	4	2	25
4110752	Medicomp® sterile	10 x 20	30	4	2	25
4116341	Medicomp® sterile OTC (ES, PT, GR, EN)	10 x 10	30	4	2	10
4116351	Medicomp® sterile OTC (ES, PT, GR, EN)	10 x 10	30	4	2	25
4116361	Medicomp® sterile OTC (ES, PT, GR, EN)	10 x 20	30	4	2	25
4116342	Medicomp® sterile OTC (ES, PT, GR, EN)	10 x 10	30	4	2	10
4116352	Medicomp® sterile OTC (ES, PT, GR, EN)	10 x 10	30	4	2	25
4116362	Medicomp® sterile OTC (ES, PT, GR, EN)	10 x 20	30	4	2	25
4110210	Medicomp® sterile (PL SR CR)	7,5 x 7,5	30	4	2	5
4110220	Medicomp® sterile (PL SR CR)	10 x 10	30	4	2	5
4110620	Medicomp® sterile (RO HU BU GR)	7,5 x 7,5	30	4	2	5
4110630	Medicomp® sterile (RO HU BU GR)	10 x 10	30	4	2	5

Products available in transport cartons without folding boxes :

REF	name	size [cm]	grammage	number of ply	pieces per pouch	pouches per transport carton
4110061	Medicomp® sterile	7.5x7.5	30	4	5	1000
4110072	Medicomp® sterile	10x10	30	4	5	1000

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 steam according to DIN EN ISO 17665-1 with validated process

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

Medicomp® sterile

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 Medicomp® sterile 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

Medicomp® sterile	
property	value
Area weight	approx. 30 g/m ² or 40 g/m ²
Water absorption capacity	approx. 7 g/g for 30 g/m ² nonwoven approx. 6,5 g/g for 40 g/m ² nonwoven
Optical brighteners	none
Chemical binders	none

Material Characteristics

Nonwoven
Mixture of viscose and polyester. The part of viscose is between 67% and 70%, the remaining part is made of polyester fibres

Labelling

Lot-No. with 9-digit code

e.g.:



9

999

01

00

1

explanation [9 = 2019]

[999-000]

definition year

serial production order

for internal purposes only

Date of manufacture

e.g.:



2019
year

04
month

01
day

Use-by date

e.g.:



2024
year

04
month

01
day

Shelf Life: 5 years

Medical Device



Medicomp® sterile

Unique Device Identifier (UDI)



Single Sterile Barrier System



Single sterile barrier system

Latest Date of Revision: 2021-03-18