

Medicomp® non sterile

General Product Description/Intended Purpose

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

Single-use, non-sterile swabs are used by lay persons and healthcare professionals on intact and injured skin to absorb body fluids (e.g. exudate or blood) or to clean the skin. They are used on injured skin as a primary or as a secondary wound dressing in combination with ointments and compression material such as bandages. A new device can be applied indefinitely.

Indication

- as a 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
- for absorption of body fluids
- as a mechanical barrier

Reference Numbers

REF	name	size [cm]	grammage	number of ply	pouches per paper bag	Paper bag per carton
4118317	Medicomp® non sterile	5x5	30	4	100	50
4118337	Medicomp® non sterile	7,5x7,5	30	4	100	50
4118338	Medicomp® non sterile	7,5x7,5	30	4	100	50
4118343	Medicomp® non sterile	7,5x10	30	4	100	50
4118354	Medicomp® non sterile	10x10	30	4	100	50
4118355	Medicomp® non sterile	10x10	30	4	100	50
4118415	Medicomp® non sterile	5x5	40	4	100	50
4118433	Medicomp® non sterile	7,5x7,5	40	4	100	50
4118442	Medicomp® non sterile	7,5x10	40	4	100	50
4118450	Medicomp® non sterile	10x10	40	4	100	50
4218218	Medicomp® non sterile	5x5	30	4	100	24
4218238	Medicomp® non sterile	7,5x7,5	30	4	100	12
4218253	Medicomp® non sterile	10x10	30	4	100	12
4218272	Medicomp® non sterile	10x20	30	4	100	6

Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

Do not use for surgical intervention.

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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® non 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® nonsterile	
property	value
Area weight	approx. 30 g/m ² or 40 g/m ²
Water absorption capacity	approx. 11 g/g for 30 g/m ² nonwoven approx. 10 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

Manufacturing Date

e.g.:		2019	04	01
		year	month	day

Use-by Date

e.g.:		2024	04	01
		year	month	day

Medicomp® non sterile

Shelf Life: 5 years

Medical Device



Unique Device Identifier (UDI)



Latest Date of Revision: 2020-11-26