

# Pagasling® (non-sterile)

## General Product Description/Intended Purpose

Pagasling® non-sterile twisted gauze sponges are manufactured from 100% cotton according to EN 14079. The sponges are made of one piece, without using a ring. Therefore its suitable for:

- non-invasive use to clean intact skin (e.g. with a disinfectant)
- non-invasive on intact or injured skin to absorb fluids (e.g. blood, exudate, etc.) or invasive in natural body cavities (oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity)
- non-invasive and invasive use as carrier material for externals (e.g. ointment) in natural body cavities (oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity)

## Application/Indication

Pagasling® sponges are single-use, non-sterile medical devices for short-term by instructed lay persons and healthcare professionals.

## Reference Numbers

REF	name	size	Gauze type	pieces per PE-Bag	pieces per folding box	PE-Bag per carton
4812900	Pagasling® (non-sterile)	Hazelnut (No.1)	20 threads	-	1000	-
4812939	Pagasling® (non-sterile)	Walnut (No.2)	20 threads	-	1000	-
4812948	Pagasling® (non-sterile)	Plum (No.3)	20 threads	500	-	2
4812993	Pagasling® (non-sterile)	Egg (No.4)	20 threads	250	-	4
4001315	Pagasling® (non-sterile)	Extra (No.5)	20 threads	250	-	4
4812954	Pagasling® (non-sterile)	Fist (No.6)	20 threads	125	-	4

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

Do not use for surgical interventions.

## 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 Pagasling® 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.

# Pagasling® (non-sterile)

## Product Performance Characteristics

Pagasling® (non-sterile)	
property	value
Sinking time	< 10 sec
Number of threads	Warp 120 ± 6/100 mm Weft 80 ± 5/100 mm
Area weight	≥ 27 g/m <sup>2</sup>
Tensile strength dry	Warp ≥ 60 N/50 mm Weft ≥ 35 N/50mm
Optical brighteners	none

## Material Characteristics

Gauze
100% chlorine free bleached cotton according EN 14079

## 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

### Expiry date

e.g.:		2024	04	01
		year	month	day

Shelf Life: 5 years

### Medical Device



### Unique Device Identification (UDI)



**Latest Date of Revision:** 2020-03-25