Product Data Sheet

1.0 Name of the product	Leukosilk®
2.0 Product description	
2.1 Description	Leukosilk® is a medical adhesive tape that consists of a non-extensible white cellulose acetate woven fabric coated on one side with a polyacrylate adhesive mass. The adhesive is cured by UV-light. The device is available in different sizes.
2.2 Intended purpose	Leukosilk® is intended for short time use on intact skin for fixation of dressings of all types and sizes and for fixation and securing of tubes, catheters, probes and cannulas. The device is non-sterile and for single application use. Intended users are health care professionals and patients. Use of the device is not restricted to specific populations.
2.3 Instructions for use	No IFU is required for this kind of product due to the low risk to user. All necessary information for safe use is available on labelling (folding box).
2.4 Warnings and precautions for use	No warnings and precautions for this device.
2.5 Contraindications	No contraindications are known for this device.
2.6 Transport Precautions	not applicable
2.7 Duration of application Period of use	The medical tape can stay on intact skin for one day to several days depending on the status of the fixated wound dressing and on the skin condition.
2.8 Composition	

Designation (incl. no. in drawing)	Description	% of final product
Backing (1)	Polyacetate fabric	58
Adhesive (2)	Polyacrylate	42
Antimicrobial spool with or without antimicrobial snapring (3)	PS & color	n.a.
Polycore	PS	n.a

2.9 Product range

Size	Color	Per folding box	Per shipper	Product code
1.25cm x 5m	White	24	240	01021-00
1.25cm x 5m		12	120	01021-02
1.25cm x 5m		24	240	01021-04
2.25cm x 5m		12	120	01022-00
2.25cm x 5m		12	120	01022-02
2.25cm x 5m		12	120	01022-03
5cm x 5m		6	60	01024-00
5cm x 5m		6	60	01024-01
1.25cm x 5m		24	240	01031-00
2.25cm x 5m		12	120	01032-00
5cm x 5m		6	60	01034-00
1.25cm x 9.2m		24	240	09566-00
2.25cm x 9.2m		12	120	09567-00
5cm x 9.2m		6	60	09569-00
1.25cm x 4.6m		24	240	72669-00
2.25cm x 4.6m		12	120	72669-01
5cm x 4.6m		6	60	72669-02

2.10 Storage conditions

cool, dry place, avoid direct sunlight

2.11 Shelf life/ Storage time

60 Months (5 years)

2.12 Key quality parameters

Characteristic	Method	Target
Adhesion to steel (jumbo)	JBS 40000083	2.50 N/cm
Adhesion to steel (final product)	JBS 40000083	2.20 N/cm

3.0 Chemical substances of special concern to Essity

Essity has defined chemical substances that are of special concern and are subject to specific restrictions. A reference to the list of substances can be found in Annex A2 via the following link www.essity.com/gss

Deviations are covered in 3.1 Components.

3.1 Components

Raw materials used in product formulation

Substance	Included in formulation
natural rubber Latex	No
Lanolin and its derivatives	No
Colophony	No
Colophony derivatives	No
Bisphenol A (BPA)	No
Polyvinylchloride (PVC)	No
Methylmethacrylate	No
Butylacrylate	No
Microplastics (<5 mm)	No
Nanoparticles	No
Fragrance/parfum	No
Antibiotics	No
Triclosan	No
Chlorhexidine	No
Polyhexanide	No

Raw materials used in the packaging

Substance	Included in formulation
Polyvinylchloride (PVC)	No
Natural rubber latex	No
Recycled material	No

Raw materials used in the product formulation and in the packaging may contain small amounts of the substances listed above and not marked as included in formulation as well as amounts of other substances not listed above. As trace level analysis is not performed for each batch BSN medical GmbH cannot provide proof of absence.

History

Version / Date	Page / Item	Description of Change
01/ 02.2021	All	New document