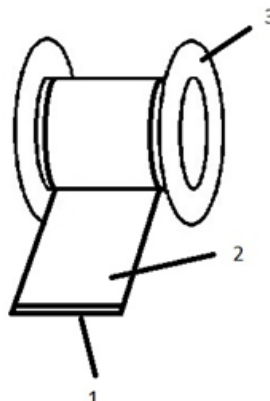


Product Data Sheet

1.0 Name of the product	Leukoflex®
2.0 Product description	
2.1 Description	Leukoflex® is a medical adhesive tape that consists of transparent polyethylene film and coated indirectly with a polyacrylate adhesive mass, then cured with UV light. The device is available in different sizes.
2.2 Intended purpose	Leukoflex® is intended for short time use on intact skin for fixation of dressings of all types and sizes, fixation of occlusive dressings and for fixation and securing of catheters, probes and cannulae. 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
2.4 Warnings and precautions for use	No warnings and precautions for his device.
2.5 Contraindications	No contraindications are known for his device.
2.6 Transport Precautions	not applicable
2.7 Duration of application	Leukoflex® is intended for short time use (< 30 days) on intact skin.

2.9 Composition



Designation (incl. no. in drawing)	Description	% of final product
Backing (1)	Polyethylene film	59
Adhesive (2)	Polyacrylate	41
Antimicrobial spool with or without antimicrobial snapping (3)	PS & color	n.a.

2.10 Product range

Size	Color	Per folding box	Per shipper	Product code
1.25 cm x 5 m	Transparent	24	240	01121-00
2.5 cm x 5 m		12	120	01122-00
5 cm x 5 m		6	60	01124-00
1.25 cm x 5 m		24	240	01131-00
2.5 cm x 5 m		12	120	01132-00
5 cm x 5 m		6	60	01134-00

2.11 Storage conditions

cool, dry place, avoid direct sunlight

2.12 Shelf life/ Storage time

60 Months (5 years)

2.13 Key quality parameters

Characteristic	Method	Target
Adhesion to steel	Essity internal	2.30 N/cm
Quantity of adhesive	Essity internal	39 g/m ²

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
Bisphenol A	No
Natural rubber latex	No
Colophonium	No
Phthalates	No
SVHC acc. REACH	No
Prop. 65	No
Heavy metals	No
Organo tin compounds	No
Animal Derived Material	No
Azo dyes	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