


## Product Data Sheet

<b>1.0 Name of the product</b>	Leukofix®																
<b>2.0 Product description</b>																	
<b>2.1 Description</b>	Leukofix® is a medical adhesive tape that consists of a transparent polyethylene film coated indirectly on one side with a polyacrylate adhesive. The adhesive is cured by UV-light. The coated jumbos are afterwards micro-perforated and then further converted on spools with or without snap rings or on polycores and packed to the final products. The product is available in different sizes																
<b>2.2 Intended purpose</b>	Leukofix® 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.																
<b>2.3 Instructions for use</b>	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																
<b>2.4 Warnings and precautions for use</b>	No warnings and precautions for this device.																
<b>2.5 Contraindications</b>	There are no known contraindications for this device.																
<b>2.6 Transport Precautions</b>	Not applicable																
<b>2.7 Duration of application</b>	All product variants of self-adhesive medical tapes as non-invasive medical devices for short term use with an intended duration of usage for not more than 30 days.																
<b>2.8 Composition</b>																	
	<table border="1"> <thead> <tr> <th>Designation (incl. no. in drawing)</th> <th>Description</th> <th>% of final product</th> </tr> </thead> <tbody> <tr> <td>Backing (1)</td> <td>Polyethylene film</td> <td>68</td> </tr> <tr> <td>Adhesive (2)</td> <td>Polyacrylate</td> <td>32</td> </tr> <tr> <td>Spool with or without snapping (3)</td> <td>Polystyrene w. antimicrobial coating</td> <td>-</td> </tr> <tr> <td>Polycore</td> <td>Polystyrene</td> <td>-</td> </tr> </tbody> </table>		Designation (incl. no. in drawing)	Description	% of final product	Backing (1)	Polyethylene film	68	Adhesive (2)	Polyacrylate	32	Spool with or without snapping (3)	Polystyrene w. antimicrobial coating	-	Polycore	Polystyrene	-
Designation (incl. no. in drawing)	Description	% of final product															
Backing (1)	Polyethylene film	68															
Adhesive (2)	Polyacrylate	32															
Spool with or without snapping (3)	Polystyrene w. antimicrobial coating	-															
Polycore	Polystyrene	-															

<b>2.9 Product range</b>	<b>Product name</b>	<b>Size/ Color</b>	<b>Per folding box</b>	<b>Per shrink</b>	<b>Per shipper</b>	<b>Product code</b>
	Leukofix Plastic Snap Ring	1.25cm x 5m	1	24	240	02121-00
		2.5cm x 5m		12	120	02122-00
		5cm x 5m		6	60	02124-00
	Leukofix Plastic Spool	1.25cm x 5m		24	240	02131-00
		2.5cm x 5m		12	120	02132-00
		5cm x 5m		6	60	02134-00
	Leukofix Plastic Core	1.25cm x 9.2m		24	240	02136-00
		2.5cm x 9.2m		12	120	02137-00
		5cm x 9.2m		6	60	02138-00
<b>2.10 Storage conditions</b>	cool, dry place, avoid direct sunlight					
<b>2.11 Shelf life/ Storage time</b>	60 months (5 years)					
<b>2.12 Sterilization</b>	Non-sterile					
<b>2.13 Key quality parameters</b>	<b>Characteristic</b>	<b>Method</b>	<b>Target</b>			
	Adhesion to steel (final product)	Essity internal	2.30 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](http://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
Lanolin and its derivatives	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 / 01.03.2021	All	Set up new document