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Product Data Sheet

1.0	Name of the product	Leukotape® Classic			
2.0	Product description				
2.1	Description	Leukotape® Classic is a rigid strapping tape which consists of woven backing material made of 100% cotton fabric (white or coloured) and coated with a natural and synthetic rubber adhesive. This zinc oxide adhesive gives Leukotape® classic an adhesion offering strong support and efficient stabilization of joint structures.			
2.2	Intended purpose	Leukotape® Classic is intended for functional taping as treatment and prevention of injuries to muscles, ligaments and joints. It's intended for rigid immobilization and for sports injuries (strains and sprains).			
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	This Inelastic tape contains natural rubber latex and natural colophony. Appropriate symbols and wording are applied to the labelling to inform the user that they may cause allergic reactions			
2.5	Contraindications	No known contraindications			
2.6	Transport Precautions	Not applicable			
2.7	Duration of application Period of use	All product variants of inelastic tapes as non-invasive medical devices for short term use (>60 min) with an intended duration of usage for not more than 30 days			
2.8	Composition	3			
		Designation	Description	% of final product	
		Fabric (1)	Cotton white or colour	49	
		Adhesive (2) Rubber based adhesive		51	
		Plastic Core (3) polystyrene copolymer - styrene/butadiene			



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		Size	Color	Per shrink	Per shipper	Product code
	Product range	2cm x 10m		12	72	01191-00
		2.5cm x 10m		12	120	01632-00
			1	12	72	01697-00
		2cm x 10m	White	5	105	01700-00
		3.75cm x 10m		5	90	01701-00
		5cm x 10m		5	45	01703-00
		2cm x 10m		5	105	02204-00
		3.75cm x 10m]	12	120	02205-00
				5	90	02206-00
		5cm x 10m]	5	45	02207-00
2.9			Black	5	90	02380-00
			Diack	12	48	02381-00
			Yellow	12	120	09263-00
		3.75cm x 10m	Red	12	120	09317-00
			Blue	12	120	09318-00
			Green	12	120	09319-00
				12	120	47109-00
		2cm x 10m	White	5	105	73488-00
		3.75cm x 10m		5	90	73488-01
		3.75cm x 10m	Blue	5	90	76185-00
			Green	5	90	76186-00
			Red	5	90	76187-00
			Yellow	5	90	76188-00
2.10	Storage conditions	To be stored in a cool dry place and protected against light.				
2.11	Shelf life/ Storage time	60 months (5 years)				
2.12	Sterilization	Non-sterile				
0.40		Characteristic Method Target				Target
2.13 Key quality parameters		Adhesion to steel (fin	nal Es	ssity internal		3.5 N/cm



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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.

Raw materials used in product formulation

Substance	Included in formulation
natural rubber Latex	Yes
Colophonium	Yes
Bisphenol A	no
Phthalates	No
SVHC acc. REACH	No
Prop. 65	No
Heavy metals	No
Organo tin compounds	No
Azo dyes	No
Animal Derived Material	No

3.1 Components

Raw materials used in the packaging

Substance	Included in formulation
Polyvinylchloride (PVC)	No
Natural rubber latex	No
Recycled material	Cardboard: yes
	Plastic: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 S.A.S cannot provide proof of absence.



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History

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