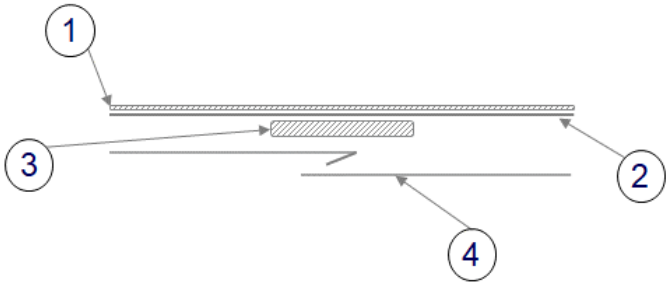
Product Data Sheet

1.0 Name of the product	Leukomed® I.V.
2.0 Product description	
2.1 Description	Leukomed® I.V. is a sterile dressing that consists of a white width wide elastic polyester non-woven backing material with a UV curing polyacrylate adhesive. The dressing has a conical cutting on one side. An absorbent wound pad is located centrally on the adhesive side. The adhesive and the wound pad are completely covered with two one sided release papers. An additional wound pad that can be used as swab, compress or cushion.
2.2 Intended purpose	Leukomed® I.V. is intended for fixation of I.V. catheters and covering and protection of puncture sites. It is to be used in children and adults in the context of intravenous therapy by trained medical professionals only. The device is sterile and for single use only.
2.3 Instructions for use	No: Instructions for use not necessary for class I/Is/IIa products. Product is self-explanatory, required symbols and pictograms for safe and efficient use on the folding box and pouch. ("Instructions for use" means instructions which have to appear on the packaging and/or a leaflet according to the European MDR)
2.4 Warnings and precautions for use	Warnings and Precautions related to the device are given in form of a symbols according to DIN EN ISO 15223 and are to read as follows: - Do not re-use - Do not use if pouch is damaged - Keep away from sunlight - Keep dry.
2.5 Contraindications	None
2.6 Transport Precautions	Not applicable
2.7 Duration of application / Period of use	One day to several days depending on the status of the wound and on the skin condition.

2.8 Composition



Designation (incl. no. in drawing)	Description	% of final product
Backing (1)	Polyester non-woven	27
Adhesive (2)	Polyacrylate adhesive	16
Wound Pad (3)	Viscose/Polypropylene non-woven	9
Release liner (4)	siliconized paper	48
Extra wound pad (20 mm x 30 mm)	Viscose/Polypropylene non-woven	n.a.

2.9 Product range

Size/ Color	Per folding box	Per shipper	Product code
6x8 cm	50	8	5072389-00

2.10 Storage conditions

cool, dry place, avoid direct sunlight

2.11 Shelf life/ Storage time

60 months (5 years)

2.12 Sterilization

EtO sterilised according to 11135:2014

2.13 Key quality parameters

Characteristic	Method	Target
Adhesion to steel (final product)	Essity internal	2.25 N/cm
Air permeability	Essity internal	> 1 cm3/cm2/s

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

List of substances that are not present in any of the products (as of November 2020)

Substance
antibiotics
Triclosan (CAS 3380-34-5)
Triclorban (CAS 101-20-2)
Silver and its compounds
Hexavalent chromium (Cr(VI)) and its compounds

Raw materials used in product formulation

Substance	Included in formulation
PVC in product	No
Softeners (Phthalates)	No
Latex Natural	No
Lanolin and lanolin derivates	No
Colophony (CAS 8050-09-7, 8052-10-6, 73138-82-6, 73905-20-1) and derivates	No
chlorhexidine	No
PHMB (CAS-nr 27083-27-8, 32289-58-0, 28757-47-3, 28757-48-4) and its compounds	No
Lead and its compounds	No
Cadmium and its compounds	No
Mercury and its compounds	No
Arsenic and its compounds	No
Organotin compounds	No
Nanomaterials	No
PVC in product	No
Softeners (Phthalates)	No

Raw materials used in the packaging

Substance	Included in formulation
PVC in packaging	No
Cellulose in packaging, bleech / recycled	Yes
Producer responsibility for waste handling	No
Sterile products offered in 3-layer concept	No

Brown cardboard in distribution packaging	Yes
Ruler on the dispensing package	No
Recycled material	Yes (Brown distribution box is partly made from recycled fiber)

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