Product Data Sheet

1.0 Name of the product	**Leukoplast® cotton wool (sterile)**
2.0 Product description	
2.1 Description	Leukoplast® cotton wool are sterile, white, absorbent cotton for single use.
2.2 Intended purpose	The device is intended for skin and wound cleansing, and absorption of secretion/exudates. The device is for short-term use. The use of device is not restricted to a specific patient population. Intended users are healthcare professionals.
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	The following symbols are used on every packaging level: • Do not use if package is damaged • Do not re-use • Do not re-sterilize
2.5 Contraindications	There are no known contraindications
2.6 Transport Precautions	Dry, clean and without exposure to direct sunlight
2.7 Duration of application	For short-term use.

2.8 Composition

Designation	Description	% of final product
Wool- ball	Cotton	100

2.9 Product range

Product code	Size	Diameter /Weight	Wool-balls per hardblister pack	blister pack per Inner shipper case	Inner shipper case (= UoM) per Outer Shipper Case	Wool balls per Shipper Case
71285-00	J(Jumbo)	3 - 5cm / 2 - 3g	5	80	2	800
71285-01	J(Jumbo)	3 - 5cm / 2 - 3g	4	80	2	640

2.10 Sizing Chart	See 2.9
2.11 Storage conditions	Dry, clean and without exposure to direct sunlight
2.12 Shelf life/ Storage time	5 years
2.13 Sterilization	EO - sterile EN 556–1, EN 556–1-BER-1, ISO 11135, EN ISO 11135
2.14 Key quality parameters	**Characteristic**: Absorption **Value**: min. 23g/g

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	Partly in Shipper and folding box

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 / 01.2023	All	Set up new document
02 / 03.2023	1.0 Name of the product	Correction
	2.9 Product range	The table has been redesigned