


Product Data Sheet

1.0 Name of the product	Elastomull®
2.0 Product description	
2.1 Description	Elastomull® is an elastic fixation bandage made of cotton, polyamide and viscose.
2.2 Intended purpose	Elastomull® is intended for fixation of wound dressings on all parts of the body and on joints. Elastomull® is non-sterile, for single use on intact skin only. Intended users are healthcare professionals and patients. Use of the device is not restricted to specific populations.
2.3 Instructions for use	Instructions for use not necessary for class I/Is/Ila products. Product is well-known and self-explanatory. Pictograms and symbols on folding box are guiding to a safe use.
2.4 Warnings and precautions for use	Do not re-use.
2.5 Contraindications	There are no known contraindications known for this product.
2.6 Transport Precautions	Not applicable
2.7 Duration of application Period of use	The bandage can remain on intact skin from one day to several days depending on the treatment needs but cumulative use can be longer than 30 days.
2.8 Information on reusable/ washable products	 for single application use only. Do not re-use.
2.9 Composition	ca. 42% cotton ca. 29% polyamide (textured) ca. 29% viscose

2.10 Product range	Size	Per folding box	Per shipper	Product code
	4cm x 4m	20	560	02094-00
	6cm x 4m	20	360	02095-00
	8cm x 4m	20	300	02096-00
	10cm x 4m	20	240	02097-00
	12cm x 4m	20	180	02098-00
	4cm x 20m	20	560	02099-00
	6cm x 20m	20	360	02100-00
	8cm x 20m	20	300	02101-00
	10cm x 20m	20	240	02102-00
	12cm x 20m	20	180	02103-00
	6cm x 20m	2	48	79996-01
	8cm x 20m	2	48	79996-02
	10cm x 20m	2	48	79996-04
	12cm x 4m	2	48	79996-05
	6cm x 4m	2	48	79996-07
	4cm x 4m	2	48	79996-08
2.11 Sizing Chart	Please see 2.10			
2.12 Storage conditions	Dry, clean and without exposure to direct sunlight			
2.13 Shelf life/ Storage time	The product has a shelf life of 5 years, if stored appropriately			
2.14 Sterilization	Non-sterile			

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	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
01/25.02.2005		Set up new document under 40002480
02/02.08.2005	Item 7	See Change Control No.: 7_348
03/25.10.2007	Item 3	Additional characteristic included
04/16.06.2014	All page 2.5/ 2 and 2.12/ 4	General revision, change from PD in PSDS Change of GMDN code and storage conditions
05/15.06.2017	Page 2 / item 2.2 Page 7 / item 4.4. Page 4 / item 2.11	Adaption to PFD JBX 40000425.05 Delete ISO 9001 Additional NARTs for Leukoplast pharmacy pack
01 / 03.03.2021	All	Set up new document according to MDR template, which will replace 40002480