

Strips Hydrogel – Class IIa

Number: TDS MC118AR11
Department: CMC-R&D
Date: 14.07.2022

1. General Product Description

Strips Hydrogel are made of transparent polyurethane gel dressing containing 60 % water and a hypoallergenic adhesive polyurethane film border. Hydrogel strips ensuring a moist wound environment. Thereby the natural healing process of the skin is accelerated.

2. Application / Intended Use

For protection and management of minor wounds, abrasions, insect bites, blisters, corns and burns.

3. Product Classification

This product is classified as nonactive medical device of class IIa according to EU Directive 93/42/EEC.

4. Presentation

Plasters packed e.g. in a folding box, plastic case or metal box.

5. Product Composition

Detailed product composition:

Backing material:	PU-film, transparent
Adhesive:	Acrylic, full-coated, transparent
Wound pad:	Hydrogel
Colour of wound pad:	Transparent or blue-dotted
Liner:	Siliconized PET
Application system:	Yes, 1,2,3-application system
Sealed wrapper:	PET/ALU/PE, printed with mandatory labelling
Sterilization:	Yes: gamma radiation

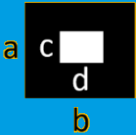



Issued by: C. Baumeister Date: August 18 th , 2020	Reviewed by: S. Wolpert Date: September 10 th , 2020	Approved by: Dr. R. Mangold Date: September 28 th , 2020
File: TPL_C1_SON_1d_Technical Data Sheet.docx	Version: 1	Effective Date: October 5 th , 2020
Copyright: CMC Consumer Medical Care GmbH	Applicable SOP: SOP_C1_SON_1_Product Development Process	Page 2/5

Strips Hydrogel – Class IIa

Number: TDS MC118AR11
 Department: CMC-R&D
 Date: 14.07.2022

6. Product Requirements

Possible dimensions:

Width (a)	Length (b)	Wound Pad (c x d)	Shape 
28 mm (± 3 mm)	68 mm (± 3 mm)	16 mm (± 2 mm) x 32 mm (± 2 mm)	
43 mm (± 3 mm)	68 mm (± 3 mm)	25 mm (± 2 mm) x 50 mm (± 2 mm)	
67 mm (± 3 mm)	110 mm (± 3 mm)	32 mm (± 2 mm) x 80 mm (± 2 mm)	

Performance data:

Parameter	Unit	Value and tolerance	Analysis method
Thickness	mm	0.9 - 1.2	Internal method
Peel adhesion	N/25 mm	8 \pm 3	EN 1939
MVTR	g/m ² /24hrs	800 \pm 200	EN 13726

Issued by: C. Baumeister Date: August 18 th , 2020	Reviewed by: S. Wolpert Date: September 10 th , 2020	Approved by: Dr. R. Mangold Date: September 28 th , 2020
File: TPL_C1_SON_1d_Technical Data Sheet.docx	Version: 1	Effective Date: October 5 th , 2020
Copyright: CMC Consumer Medical Care GmbH	Applicable SOP: SOP_C1_SON_1_Product Development Process	Page 3/5

Technical Data Sheet



Strips Hydrogel – Class IIa

Number: TDS MC118AR11
Department: CMC-R&D
Date: 14.07.2022

7. Coding

Lot-coding with 9-digit code: Y XXX WW XXX

1	XXX	47	XXX
year	for internal purposes only	week of production	for internal purposes only

Expiry date: 3 years

Coding with 6-digit code: YYYY-MM

2025	06
year	month

8. Storage

Store in a cool, dry and clean place, away from direct sunlight.

Date: 14.07.2022

i.V. S. Wolpert

CMC – R&D

i.V. C. Baumeister

Subscribed by CMC – R&D

Issued by: C. Baumeister Date: August 18 th , 2020	Reviewed by: S. Wolpert Date: September 10 th , 2020	Approved by: Dr. R. Mangold Date: September 28 th , 2020
File: TPL_C1_SON_1d_Technical Data Sheet.docx	Version: 1	Effective Date: October 5 th , 2020
Copyright: CMC Consumer Medical Care GmbH	Applicable SOP: SOP_C1_SON_1_Product Development Process	Page 4/5