

# Technical Data Sheet



## 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 <sup>th</sup> , 2020	Reviewed by: S. Wolpert Date: September 10 <sup>th</sup> , 2020	Approved by: Dr. R. Mangold Date: September 28 <sup>th</sup> , 2020
File: TPL_C1 SON_1d_Technical Data Sheet.docx	Version: 1	Effective Date: October 5 <sup>th</sup> , 2020
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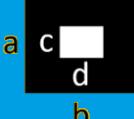
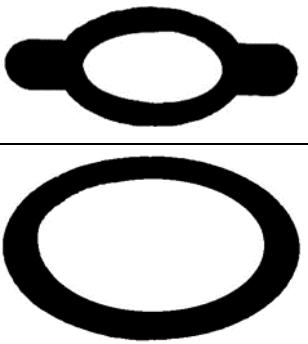
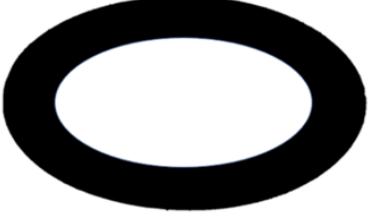


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### 6. Product Requirements

Possible dimensions:

Width (a)	Length (b)	Wound Pad (c x d)	Shape
28 mm ( $\pm 3$ mm)	68 mm ( $\pm 3$ mm)	16 mm ( $\pm 2$ mm) x 32 mm ( $\pm 2$ mm)	
43 mm ( $\pm 3$ mm)	68 mm ( $\pm 3$ mm)	25 mm ( $\pm 2$ mm) x 50 mm ( $\pm 2$ mm)	
67 mm ( $\pm 3$ mm)	110 mm ( $\pm 3$ mm)	32 mm ( $\pm 2$ mm) x 80 mm ( $\pm 2$ 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 <sup>2</sup> /24hrs	800 $\pm$ 200	EN 13726

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### 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*  
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CMC – R&D

*i.V. C. Baumeister*  
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Subscribed by CMC – R&D

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