

PermaFoam Classic® Border PermaFoam Classic® Non-border	Spec.-No.:	D 71603-01
	Department:	CEO-DAW
	Date:	2019-07-24

1. General Product Description

PermaFoam classic® Non-border

PermaFoam Classic is a hydrophilic polymer with a three-dimensional foam structure which can effectively absorb wound exudate and maintain a moist wound environment.

PermaFoam classic® Border

PermaFoam Classic Border also has an adhesive border coated with a polyacrylate adhesive.

Legal manufacturer of the product according to Medical Device Regulation respectively is the supplier Huizhou Foryou Medical Devices Co., Ltd.

The product is legally placed on the market by the supplier.

The products will be sold under the PH Brand "PermaFoam Classic"

The product has to comply with the relevant requirements of the Medical Device Regulation for Class IIb sterile medical devices.

The supplier is responsible for the technical documentation, registration, CE-marking, fulfilment of the essential requirements and the risk assessment procedure.

The supplier Huizhou Foryou Medical Devices Co., Ltd provides PHAG with relevant parts of the said technical documentation.

2. Application / Indication

PermaFoam Classic is a sterile, non-medicated single-use polyurethane foam dressing with a three-dimensional foam structure which can effectively absorb wound exudate and maintain a moist wound environment.

The product is indicated for medium to highly exuding, acute and chronic wounds, such as venous ulcers (leg ulcers), pressure ulcers II-IV, diabetic foot ulcers, donor sites, abrasions, incisions.

PermaFoam Classic Border also has an adhesive border coated with a polyacrylate adhesive.

PermaFoam Classic is used by healthcare professionals and can be applied for up to 30 days.

3. Presentations

Sterile, individually sealed

Type	Dimensions (cm)	Dimensions of wound pad (cm)
PermaFoam® Classic Border	10 x 10	5 x 5
PermaFoam® Classic Border	15 x 15	10 x 10
PermaFoam® Classic Border	30 x 10	24 x 5
PermaFoam® Classic Concave	16,5 x 18	10,5 x 12
PermaFoam® Classic Sacral	18 x 18	11,5 x 9,5
PermaFoam® Classic Sacral	22,5 x 22,5	13,5 x 11,5
PermaFoam® Classic	10 x 10	10 x 10
PermaFoam® Classic	15 x 15	15 x 15
PermaFoam® Classic	20 x 10	20 x 10
PermaFoam® Classic	20 x 20	20 x 20
PermaFoam® Classic (round)	Ø 6 (round)	Ø 6 (round)
PermaFoam® Classic Tracheostomy	8 x 8	8 x 8

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Technical Data Sheet

PermaFoam Classic® Border
PermaFoam Classic® Non-border

Spec.-No.:	D 71603-01
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4. Product characteristics

Material composition:

PermaFoam® Classic Border

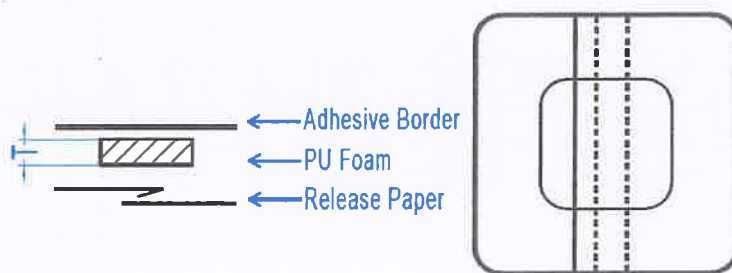
Adhesive Border	Elastic, water-vapor permeable top-layer made of polyurethane and acrylic adhesive
Absorbing foam	Soft, absorbent foam made of polyurethane
Release Paper	Glassine

Product drawing:

Classic Border:

Side View

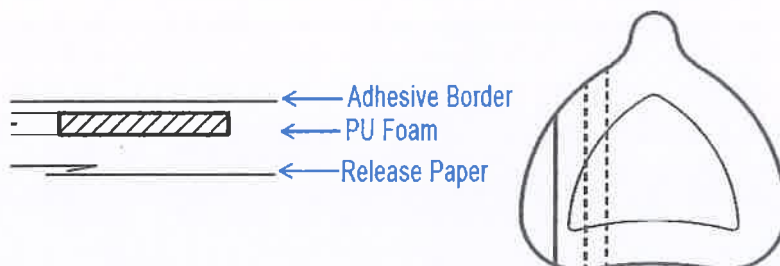
Bottom View



Classic Sacral:

Side View

Bottom View



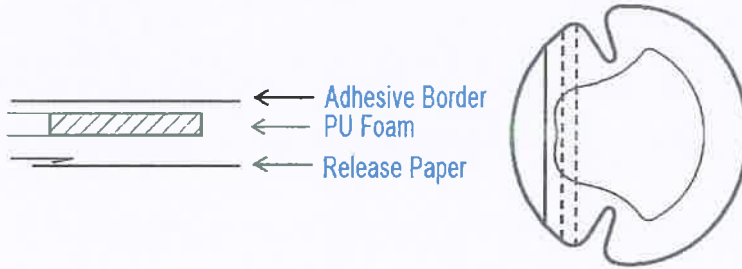
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Classic Concave:

Side View

Bottom View



PermaFoam® Classic

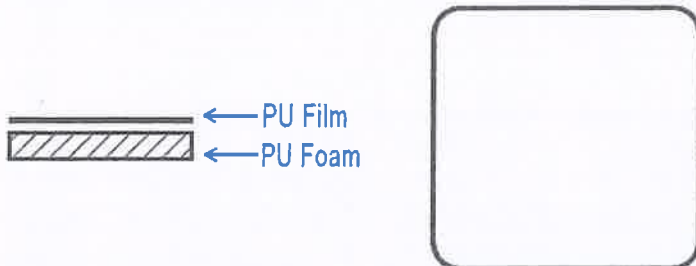
Film	Elastic, water-vapour permeable top-layer made of polyurethane and acrylic adhesive
Absorbing foam	Soft, absorbent foam made of polyurethane

Product drawing:

Classic:

Side View

Bottom View



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Technical Data Sheet

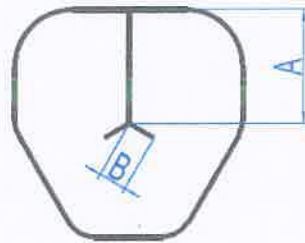
PermaFoam Classic® Border
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Tracheostomy:

Side View

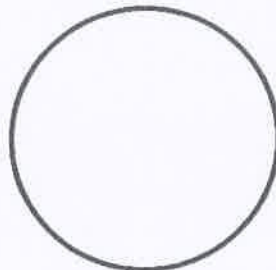
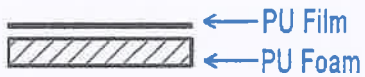
Bottom View




Round:

Side View

Bottom View



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5. Product Requirements

PermaFoam® Classic Border / Classic

	PermaFoam® Border	PermaFoam® Classic
Absorption	>10 g/g	>10 g/g
Moisture vapor transmission	>600 g/m ² /24h	>1600 g/m ² /24h
Absorbent Under 40mmHg Load	>3 g/g	>3 g/g

6. Labelling

The Lot number is created by production department and entry into our ERP system (E10).

Example:

Lot. - No.	19	06	0234
Explanation	[19 = 2019]	[01 - 12]	[0001 - 9999]
Definition	The current year	Production Month	Production serial number

The lot number is printed on all packaging levels near the symbol in the frame intended to variable data mentioned

Expiry date (including print on iLISS-Labels for transport carton)

The expiry date is composed of 8 digits and is set up as follows:

Year (4 digits) - month (2 digits) – day (2 digits)

Separation of year, month and day happens by hyphen.

Example: 2024-03-01

The expiry date depends on the day of production (instead of always using "01" for the day of production) and changes within the actual production date.

The guaranteed shelf life is 3 years.

The expiry date is printed near the symbol in the frame intended to variable data*.

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7. Packaging

PermaFoam® Classic Border / Classic is individually sealed into a peel pouch, peel pouches are packaged in a folding box; boxes are packaged in a transport carton acc. DIN, sealed with adhesive tapes, packed onto euro pallet.

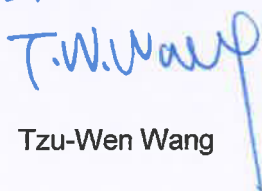
8. Latex and Phthalate

The product as well as packaging materials for all packaging levels don't contain any natural rubber (latex) and phthalate.

Date: 2019-07-24

PAUL HARTMANN AG
 - CEO-DAW
 - Product Development Wound Management

Issued by:

i. A.
 24.07.2019

 Tzu-Wen Wang

Approved by:

Legal Manufacturer: Huizhou Foryou Medical

 Xiang Gao, Product Engineer

, LTD