

# Technical Data Sheet

## Plum QuickFix Blood Stopper

### 1. Identification of the product and the company

#### 1.1 Product identifier and intended use

<b>Trade Name:</b>	Plum QuickFix Blood Stopper
<b>Intended Use:</b>	Plum QuickFix Blood Stopper plaster is intended to control the wound microenvironment with hemostatic action to limit bleeding over time and accelerate the coagulation process. The action is combined with the generation of a moist microenvironment that promotes the healing process.
<b>Expiry date:</b>	Printed on the back of the plaster.




#### 1.2 Details of the supplier of the data sheet

<b>Manufacturer</b>	
<b>Company:</b>	Plum Safety ApS
<b>Address:</b>	Mandelalléen 1
<b>Zip code:</b>	5610
<b>City:</b>	Assens
<b>Country:</b>	DENMARK
<b>E-mail:</b>	<a href="mailto:info@plum.eu">info@plum.eu</a>
<b>Phone:</b>	+45 6916 9600
<b>Fax:</b>	+45 6916 9630

#### 1.3 Legislative information

<b>General information:</b>	<p>As the products are class IIa medical devices according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices concerning medical devices, they are certified by Notified body, Kiwa Cermet Italia S.p.A.</p> <p>No Safety Data Sheet is required for medical devices.</p> <p>Plum Safety ApS is certified according to <i>ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes</i>.</p> <p>Plastod S. p. A. Via Walter Masetti 7, 40012 Calderara di Reno (BO), Italy is the legal manufacturer of QuickFix Blood Stopper.</p>
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#### 1.4 Symbol explanation

- Paper wrapping contains rubber latex 
- Do not reuse 
- Do not use if package is damaged 

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### 2. General information about the product

**Material requirements:**

The materials in these products have been judged biocompatible according to the requirements of *EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

**Physical properties and composition:**

	Blood Stopper
Material	<i>Pink cross direction elastic fabric (65% cotton &amp; 35% polyamide)</i>
Adhesive pad	<i>Hypoallergenic acrylic polymer</i>
Absorbing pad	<i>Viscose and PP/PE non-woven with haemostatic layer (calcium-sodium alginate particles) and anti-adhering layer (polyester net)</i>
Primary Packing (Pouch)	<i>Cold sealed paper</i>
Dimensions	<i>72 x 25 mm</i>
Special feature	<i>Haemostatic effect Breathable</i>

### 3. Side effects and malfunction

**Side effects and malfunction:**

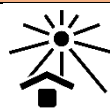
The products are designed for skin contact and first aid use involving minor wounds. If side effects or malfunctions are experienced, please report these to Plum Safety ApS, [info@plum.eu](mailto:info@plum.eu) or phone +45 6471 2112, so that necessary remedial measures can be initiated.

Serious adverse effects should always be reported to a relevant and competent authority.

### 4. Storage

**Storage:**

Keep dry



Keep away from sunlight

**Shelf life:**

5 years from production date.

### 5. Other information

**Version history and indication of changes**

Version	Revision date (dd-mm-yyyy)	Responsible	Changes
2.0	08-08-2025	MAW	1.4 + 2
1.5	20-06-2025	MAW	1.3 + 2
1.4	17-10-2023	ANS	1.3

*Information on earlier revisions to be found on document version 1.4 or earlier*

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**Other information** Additional information can be obtained by contacting [info@plum.eu](mailto:info@plum.eu) or by telephone +45 6471 2112.

**TDS prepared by:**

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