

# Technical Data Sheet

## QuickFix

(aloe vera, blood stopper)

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

#### 1.1. Product identifier and intended use.

Trade Name:	QuickFix
Intended Use:	Plum QuickFix products are intended for use as a mechanical barrier for absorption of exudates from minor wounds.
Expiry date:	Printed on the back of the plaster and device cover

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

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

#### 1.3 Legislative information

General information:	<p>As the products are class 2a medical devices according to <i>Council Directive 93/42/EEC of 14 June 1993</i> 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 Caldata di Reno (BO), Italy is the legal manufacturer of QuickFix aloe vera and QuickFix blood stopper.</p>
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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 <i>ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process</i> .
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#### Physical properties and composition:

	aloe vera	blood stopper
Material	<i>Pink cross direction elastic fabric (Cotton &amp; polyamide)</i>	<i>Pink cross direction elastic fabric (Cotton &amp; polyamide)</i>
Adhesive pad	<i>Hypoallergenic acrylic polymer</i>	<i>Hypoallergenic acrylic polymer</i>
Absorbing pad	<i>Viscose and PP non-woven with aloe vera</i>	<i>Viscose and PP/PE non-woven with haemostatic layer and alginate fibres.</i>
Primary Packing (Pouch)	<i>Cold sealed paper</i>	<i>Cold sealed paper</i>
Dimensions	<i>72 x 25 mm</i>	<i>72 x 25 mm</i>
Special feature	<i>Soothing and moisturizing</i>	<i>Haemostatic effect</i>

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### 3. Side effects and malfunction

**Side effects and malfunction:**

The products are designed for 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 6916 9600, 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	Responsible	Changes
1.3	25-05-2021	CL	1.2, 1.3, 3, 5
1.2	30-09-2020	CL	5
1.1	12-06-2020	CL / VWB	5
1.0	14-04-2020	CL / VWB	

**Other information**

Additional information can be obtained by contacting [info@plum.eu](mailto:info@plum.eu) or by telephone +45 6916 9600.

**TDS prepared by:**

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