

Technical Data Sheet

QuickFix

(elastic, detectable, water resistant & alu)

1. Identification of the product and the company

1.1. Product identifier and intended use.

Trade Name:	QuickFix and QuickFix Long
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.

1.2. Details of the supplier of the data sheet

Manufacturer	
Company:	Plum Safety ApS
Address:	Mandelalleen 1
Zip code:	5610
City:	Assens
Country	DENMARK
E-mail	info@plum.eu
Phone	+45 6916 9600
Fax	+45 6916 9630

1.3 Legislative information

General information:	As the products are class 1 medical devices according to <i>Council Directive 93/42/EEC of 14 June 1993</i> concerning medical devices. No notified body is involved. No Safety Data Sheet is required for medical devices.
	Plum Safety ApS is certified according to <i>ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes</i> .

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:

	elastic	detectable	water resistant	alu
Material	<i>Pink cross direction elastic fabric (Cotton & polyamide)</i>	<i>Blue cross direction elastic fabric (Cotton & polyamide)</i>	<i>Pink perforated PE (Polyethylene)</i>	<i>Pink cross direction fabric (Cotton & polyamide)</i>
Adhesive pad	<i>Hypoallergenic acrylic polymer</i>	<i>Hypoallergenic acrylic polymer</i>	<i>Hypoallergenic acrylic polymer</i>	<i>Hypoallergenic acrylic polymer</i>
Absorbing pad	<i>Viscose and non-woven PP</i>	<i>Viscose and PP/PE non-woven</i>	<i>Viscose and non-woven PP</i>	<i>Viscose and aluminium coated PE non-woven</i>
Primary Packing (Pouch)	<i>Cold sealed paper</i>	<i>Cold sealed paper</i>	<i>Cold sealed paper</i>	<i>Cold sealed paper</i>
Dimensions	<i>72 x 25 mm 120 x 20 mm</i>	<i>72 x 25 mm 120 x 20 mm</i>	<i>72 x 25 mm</i>	<i>72 x 25 mm</i>
Special feature	<i>Elastic</i>	<i>Elastic Detectable aluminium foil facing the backing</i>	<i>Water resistant</i>	<i>Elastic Anti-adhering effect</i>

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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 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	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	5
1.0	14-04-2020	CL	

Other information

Additional information can be obtained by contacting info@plum.eu or by telephone +45 6471 2112.

TDS prepared by:

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