

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 A/S
Address:	Frederik Plums Vej 2
Zip code:	5610
City:	Assens
Country:	DENMARK
E-mail:	info@plum.eu
Phone:	+45 64712112
Fax:	+45 64712125

1.3 Legislative information

General information: As the products are class 1 medical devices according to *Council Directive 93/42/EEC of 14 June 1993* concerning medical devices. No notified body is involved. No Safety Data Sheet is required for medical devices.

Plum A/S is certified according to *ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes*.

2. General information about the product

Material requirements: The materials in these products has been judged biocompatible according the requirements of *ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*.

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 A/S, info@plum.eu or phone +45 6471 2112, so that necessary remedial measures can be initiated.

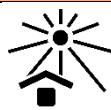
Serious adverse effects should always be reported to a relevant and competent authority.

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
1.2	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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