

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 *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 Safety ApS 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 have been judged biocompatible according to 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	Pink cross direction elastic fabric (Cotton & polyamide)	Blue cross direction elastic fabric (Cotton & polyamide)	Pink perforated PE (Polyethylene)	Pink cross direction fabric (Cotton & polyamide)
Adhesive pad	Hypoallergenic acrylic polymer	Hypoallergenic acrylic polymer	Hypoallergenic acrylic polymer	Hypoallergenic acrylic polymer
Absorbing pad	Viscose and non-woven PP	Viscose and PP/PE non-woven	Viscose and non-woven PP	Viscose and aluminium coated PE non-woven
Primary Packing (Pouch)	Cold sealed paper	Cold sealed paper	Cold sealed paper	Cold sealed paper
Dimensions	72 x 25 mm 120 x 20 mm	72 x 25 mm 120 x 20 mm	72 x 25 mm	72 x 25 mm
Special feature	Elastic	Elastic Detectable aluminium foil facing the backing	Water resistant	Elastic Anti-adhering effect

Technical Data Sheet

QuickFix

(elastic, detectable, water resistant & alu)

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.

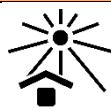
Serious adverse effects should always be reported to a relevant and competent authority.

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:

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



Document Language: English