Technical Data Sheet

OuickFix

(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	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

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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
1.0	19-11-2019	CL	New TDS

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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Document Language: English