

Technical Data Sheet

Plum QuickFix Aloe Vera

1. Identification of the product and the company

1.1 Product identifier and intended use

Trade Name:	Plum QuickFix Aloe Vera
Intended Use:	Plum QuickFix Aloe Vera plaster is intended to control the wound microenvironment by generation of a moist environment.
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:	Mandelalléen 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 IIa medical devices according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices concerning medical devices, they are certified by Notified body, Kiwa Cermet Italia S.p.A.

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*.

Plastod S. p. A. Via Walter Masetti 7, 40012 Calderara di Reno (BO), Italy is the legal manufacturer of QuickFix Aloe Vera.

1.4 Symbol explanation

- Paper wrapping contains rubber latex 
- Do not reuse 
- Do not use if package is damaged 

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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 *EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Physical properties and composition:

	Aloe Vera
Material	<i>Pink cross direction elastic fabric (65% cotton & 35% polyamide)</i>
Adhesive pad	<i>Hypoallergenic acrylic polymer</i>
Absorbing pad	<i>Viscose and PP non-woven with 1,5% aloe vera</i>
Primary Packing (Pouch)	<i>Cold sealed paper</i>
Dimensions	<i>72 x 25 mm</i>
Special feature	<i>Soothing and moisturizing Breathable</i>

3. Side effects and malfunction

Side effects and malfunction:

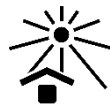
The products are designed for skin contact and first aid use involving minor wounds. If side effects or malfunctions are experienced, please report these to Plum Safety ApS, info@plum.eu or phone +45 6471 2112, so that necessary remedial measures can be initiated.

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 (dd-mm-yyyy)	Responsible	Changes
2.0	08-08-2025	MAW	1.4 + 2
1.5	20-06-2025	MAW	1.3 + 2
1.4	17-10-2023	ANS	1.3

Information on earlier revisions to be found on document version 1.4 or earlier

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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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