Technical Data Sheet

Pull1Aid® Blood Stopper 4-in-1

1. Identification of the product and the company

1.1. Product identifier and intended use.

Trade Name:	Pull1Aid® Blood Stopper 4-in-1 Mini / Pull1Aid® Blood Stopper 4-in-1
Intended Use:	Plum Pull1Aid® Blood Stopper 4-in-1 is intended to be used as a mechanical barrier and compression.
Expiry date:	Printed on the sealed package.

1.2. Details of the supplier of the data sheet

Distributor	
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 1s sterile medical devices according to *Council Directive 93/42/EEC of 14 June 1993* concerning medical devices, they are certified by the Notified Body, Intertek Semko AB, Kista, Sweden. No Safety Data Sheet is required for medical devices. AKLA AB, Enghagslingan 2, 187 40 Täby, Sweden is the legal manufacturer of Pull1Aid® Blood Stopper 4-in-1 Mini and Pull1Aid® Blood Stopper 4-in-1. 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:

	Pull1Aid® Blood Stopper 4-in-1 Mini Art. No. 5153 (REF. 92109)	**Pull1Aid® Blood Stopper 4-in-1 Art. No. 5154 (REF 92111PM)**
Material	*Nonwoven dressing, small, in CELLOSOFT-material,3-layer combination of: 100%LDPE-HDPE 30g/m² micro perforated. 100% Viscose 200 g/m² +/- 10% 100% LDPE-HDPE 30g/m² micro perforated non-adhesive, stitched on elastic bandage 2m x 6cm.*	*Nonwoven dressing, large, in CELLOSOFT-material: 70%Viscose. 30% Polythylene non-adhesive, stitched on elastic bandage 4m x 6cm, Extra bandage 3m x 6cm Bandage: Polyamid 60%/Viscose 40%.*
Primary Packing (Pouch)	*Cold sealed paper*	*Cold sealed paper*
Secondary Packing (Box)	21 PAP	21 PAP
Absorption	*≥ 6g/g*	*≥800g/m²*
Dimensions	*7,5 x 12cm (3 pcs)*	*17 x 17 cm*
Special feature	*Suitable for hand, finger and toes*	*Suitable as pressure bandage, protective dressing.*

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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 wounds.
If side effects or malfunctions are experienced, please report these to Plum Safety ApS, info@plum.eu or phone +45 6916 9600, so that necessary remedial measures can be initiated.
Reporting of accidents and incidents. Vigilance. Serious incidents involving products made available on the EU market must be reported immediately to the National Competent Authority. All serious incidents must be reported no later than 15 days after discovery, in the event of a serious threat to public health within 2 days. In the event of death or an unexpected and serious deterioration of a person's state of health, reporting must take place within 10 days.

4. Storage

Shelf life: 5 years from production date

5. Other information

Do not reuse:

Do not use if package is damaged

Version history and indication of changes

Version	Revision date	Responsible	Changes
1.0	20-06-2022	CL	

Other information Additional information can be obtained by contacting info@plum.eu or by telephone +45 6916 9600.

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