

Technical Data Sheet

Plum Wound and Eyewash 0.9% Sodium Chloride

1. Identification of the product and the company

1.1 Product identifier and intended use

Trade Name: Plum Wound and Eyewash 0.9% Sodium Chloride and Plum Wound and Eyewash 0.9% Sodium Chloride QuickRinse.

Intended Use: Plum Wound and Eyewash 0.9% Sodium Chloride is a sterile first aid product that rinses and irrigates the dirt, dust, liquid and foreign body from wounds and eyes.

Expiry date: Printed on the bottle label.

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 IIb medical devices according to *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices*, they are certified by the Notified Body, **DNV Product Assurance AS**.

No Safety Data Sheet is required for medical devices.

The products shall not be classified as hazardous according to the classification and labeling rules for substances and mixtures.

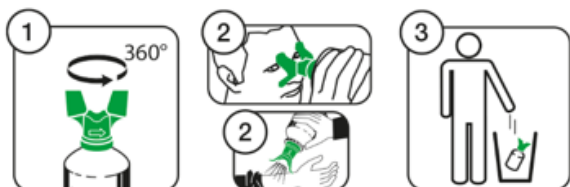
Plum Safety ApS is certified according to *ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes*.

1.4 Instructions for use

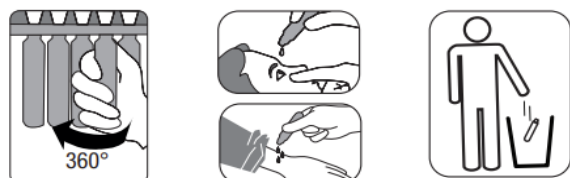
Mono eyecup (200, 500, 1000 ml)



DUO eyecup (500, 1000 ml)



QuickRinse (20 ml)



Technical Data Sheet

Plum Wound and Eyewash 0.9% Sodium Chloride

1.5 Symbol explanation

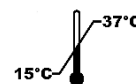
- Do not reuse



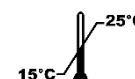
- Do not use if package is damaged



- Recommended temperature when used



- Recommended temperature when used (only applicable for QuickRinse)



- Single sterile barrier system



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*.

Bottle, label and eyecup dimensions

	20 ml	200 ml	500 ml	1000 ml
Bottle material	Polyethylene without additives	Polyethylene without additives	Polyethylene without additives	Polyethylene without additives
The bottle contains [ml]	20.0-20.5	201-207	505-512	1005-1020
Bottom Ø [mm]	21	58.5	78	90
Height [mm]	125	165	220	260

3. Side effects and malfunction

Side effects and malfunction:

The products are designed as a first aid product for wounds and eyes irrigation involving accidents with acids and alkali. 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.

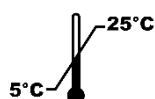
Serious adverse effects should always be reported to a relevant and competent authority.

4. Storage

Storage:



Upper and lower temperature limit



Upper and lower temperature limit (only applicable for QuickRinse)

Shelf life:

42 months for Plum Wound and Eyewash and 60 months for Plum Wound and Eyewash QuickRinse from date of manufacture.

Installation:

Please refer to the pictogramm on the label:



Technical Data Sheet

Plum Wound and Eyewash 0.9% Sodium Chloride

5. Other information

Version history and indication of changes

Version	Revision date (dd-mm-yyyy)	Responsible	Changes
2.0	14-10-2025	MAW	1.4 + 1.5 + 2 + 4
1.6	27-11-2024	MAW	1.4
1.5	17-10-2023	ANS	1.1, 1.3, 1.4, 2.0

Information on earlier revisions to be found on document version 1.5 or earlier

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

TDS prepared by:

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

Document Language: English