Technical Data Sheet
Plum Eyewash 0.9% Sodium Chloride

1. Identification of the product and the company

1.1. Product identifier and intended use.

Trade Name:	Plum Eyewash 0.9% Sodium Chloride and Plum Eyewash 0.9% Sodium Chloride QuickRinse
Intended Use:	The products are intended to be used as first aid products for eye irrigation.
Expiry date:	Printed on the bottle label/ampoule.

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:

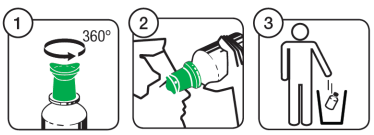
As the products are class 1s sterile medical devices according to *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*, they are certified by the Notified Body, **DNV Product Assurance AS**. No Safety Data Sheet is required for medical devices.

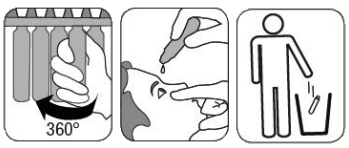
The products shall not be classified as hazardous according to the classification and labeling rules for substance and mixtures.

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

1.4 Instruction for use:

Mono eye cup (200, 500, 1000 ml)



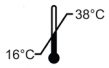


Duo eye cup (500, 1000 ml)



Ampoule (20 ml)

- Do not reuse.
- Do not use if damaged.
- Recommended temperature when used



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2. General information about the product

Material requirements: The materials in these products have 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.*

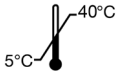
Bottle, label and eye cup dimensions.

	20 ml ampoule	200 ml bottle	500 ml bottle	1000 ml bottle
Bottle material	Polyethylene without additives	Polyethylene without additives	Polyethylene without additives	Polyethylene without additives
The bottle/ampoule contains [ml]	20.0-20.5	201-207	505-512	1005-1020
Bottom Ø [mm]	21	58.5	78	90
Height [mm]	104	129.6	183	229

3. Side effects and malfunction

Side effects and malfunction: The products are designed as a first aid product for eye irrigation. 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 competent authority.

4. Storage

Storage: 

Shelf life: 42 months from manufacturing date.

Installation: Please refer to the pictogramm on the label: 

Mounting stations and boxes: Please visit https://plum.eu/products/firstaid/eye-wash

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	03-06-2020	CL / VWB	5
1.0	14-04-2020	CL /VWB	

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

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