

Technical Data Sheet

Plum QuickClean

1. Identification of the product and the company

1.1 Product identifier and intended use

Trade Name: Plum QuickClean.

Intended Use: Plum QuickClean is a sterile first aid product that rinses and irrigates the dirt, dust, liquid and foreign body from wounds.

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

As the products are class Is sterile medical devices according to *Council Directive 93/42/EEC of 14 June 1993 and MDR2017/745 art. 120* concerning medical devices, they are certified by the Notified Body, Intertek Medical Notified Body AB, Kista, Sweden.

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*.

AKLA AB, Parkgatan 15, 696 33 Askersund, Sweden is the legal manufacturer of Plum QuickClean.

2. General information about the product

Material requirements: The materials in these products have been judged biocompatible according to the requirements of *ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.

Physical properties and composition

	Plum QuickClean Art. No. 5151/5551 (REF 94407ST)
Material	<i>Nonwoven tissue</i> <i>Ingredients: Aqua sterile</i>
Primary Packing (Multi layered pouch)	
Secondary Packing (Box)	
Dimensions	<i>Tissue: 200x130 mm unfolded</i> <i>Primary package: 60x75 mm</i>

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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 cleansing of small 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



Sterilized using irradiation

**Version history and indication of changes**

Version	Revision date (dd-mm-yyyy)	Responsible	Changes
1.0	14-04-2026	MAW	-

Other information

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

TDS prepared by:

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