EU Declaration of Conformity

Manufacturer:	Plum Safety ApS Mandelalléen 1, 5610 Assens Denmark
SRN (Single Registration Number):	DK-MF-000008672
Name of the product:	Plum Wound and Eyewash 0.9% Sodium Chloride

Reference number:

Art No	Art Name	Volume
5160	Plum Wound and Eyewash 0.9% Sodium Chloride QuickRinse	20 ml
4691	Plum Wound and Eyewash 0.9% Sodium Chloride	200 ml
4604	Plum Wound and Eyewash 0.9% Sodium Chloride	500 ml
4707	Plum Wound and Eyewash 0.9% Sodium Chloride	1000 ml
4861	Plum Wound and Eyewash 0.9% Sodium Chloride DUO	500 ml
4800	Plum Wound and Eyewash 0.9% Sodium Chloride DUO	1000 ml

Intended purpose:	Plum Wound and Eyewash 0.9% Sodium Chloride is a sterile first aid product that rinses and irrigates the dirt, dust, liquid and foreign objects from wounds and eyes.
Basic UDI-DI:	5715205EYEWASH0.9%H5
Device classification:	Class IIb, according to Annex VIII, Rule 21
Notified Body:	DNV Product Assurance AS
Notified Body Identification Number:	2460

This declaration of conformity is issued under the sole responsibility of Plum Safety ApS. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices, including the conformity assessment procedure specified in Annex IX, excl. Chapter II (certificate No.: C590336).

This declaration is supported by the Quality System approval to ISO 13485 issued by DNV Product Assurance AS, Certificate No.: 10000478596-PA-NA-DNK.

All supporting documentation is retained at the premises of the manufacturer.

The medical devices comply with the state-of-the-art requirements referred to in the standards mentioned in the current edition of the Technical Documentation.

Reference to common specifications: Not Applicable

Signature for Plum Safety ApS:

Place and date:

Sep 26, 2025

Jonas Skov

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Jonas Skov
Person Responsible for Regulatory Compliance

DoC Plum Wound and Eyewash 0.9_ Sodium Chloride 2025

Final Audit Report 2025-09-26

Created:	2025-09-26
By:	Amalie Storm (ans@plum.eu)
Status:	Signed
Transaction ID:	CBJCHBCAABAAOLNIR63P7vjQ5LMW5gcACoAoW8PYANUW

"DoC Plum Wound and Eyewash 0.9_ Sodium Chloride 2025" History

Document created by Amalie Storm (ans@plum.eu)
2025-09-26 - 10:13:02 AM GMT

Document emailed to Jonas Skov (jos@plum.eu) for signature
2025-09-26 - 10:13:26 AM GMT

Email viewed by Jonas Skov (jos@plum.eu)
2025-09-26 - 10:13:52 AM GMT

Document e-signed by Jonas Skov (jos@plum.eu)
Signature Date: 2025-09-26 - 10:14:03 AM GMT - Time Source: server

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EU Declaration of Conformity

Manufacturer:	Plum Safety ApS Mandelalléen 1, 5610 Assens Denmark
SRN (Single Registration Number):	DK-MF-000008672
Name of the product:	Plum Wound and Eyewash pH Neutral 4.9% Phosphate
Reference number:	

Art No	Art Name	Volume
4752	Plum Wound and Eyewash pH Neutral 4.9% Phosphate	200 ml
4801	Plum Wound and Eyewash pH Neutral 4.9% Phosphate DUO	500 ml

Intended purpose:	Plum Wound and Eyewash pH Neutral 4.9% Phosphate is a first aid product for wound and eye irrigation involving accidents with acids and alkali.
Basic UDI-DI:	5715205PHNEUTRAL4.9%P6
Device classification:	Class IIb, according to Annex VIII, Rule 21
Notified Body: Notified Body Identification Number:	DNV Product Assurance AS 2460

This declaration of conformity is issued under the sole responsibility of Plum Safety ApS. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices, including the conformity assessment procedure specified in Annex IX, excl. Chapter II (certificate No.: C590336).
This declaration is supported by the Quality System approval to ISO 13485 issued by DNV Product Assurance AS, Certificate No.: 10000478596-PA-NA-DNK.
All supporting documentation is retained at the premises of the manufacturer.
The medical devices comply with the state-of-the-art requirements referred to in the standards mentioned in the current edition of the Technical Documentation.
Reference to common specifications: Not Applicable

Signature for Plum Safety ApS:

Place and date:

Sep 26, 2025

Jonas Skov

.....

Jonas Skov
Person Responsible for Regulatory Compliance

DoC Plum Wound and Eyewash pH Neutral 4.9_ Phosphate 2025

Final Audit Report 2025-09-26

Created:	2025-09-26
By:	Amalie Storm (ans@plum.eu)
Status:	Signed
Transaction ID:	CBJCHBCAABAA4G8lubj92dbMKRtZVjPZpCG4PpCNitQ2

"DoC Plum Wound and Eyewash pH Neutral 4.9_ Phosphate 2025" History

Document created by Amalie Storm (ans@plum.eu)
2025-09-26 - 10:13:58 AM GMT

Document emailed to Jonas Skov (jos@plum.eu) for signature
2025-09-26 - 10:14:27 AM GMT

Email viewed by Jonas Skov (jos@plum.eu)
2025-09-26 - 10:15:14 AM GMT

Document e-signed by Jonas Skov (jos@plum.eu)
Signature Date: 2025-09-26 - 10:15:23 AM GMT - Time Source: server

Agreement completed.
2025-09-26 - 10:15:23 AM GMT

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