CE DECLARATION OF CONFORMITY

Plum Eyewash 0.9% Sodium Chloride

Eye irrigation fluid for first aid

We, the manufacturer, of the products covered by this declaration, hereby declare, that the bottles with sterile irrigation fluid listed below, meet the requirements in the Council Directive 93/42/EEC of 14 June 1993, the Directive 2007/47 /EC and its relevant transposition into national laws of the member states into which we place the device. Plum Safety ApS is responsible for the Declaration of Conformity concerning the medical devices listed below:

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

With the intended purpose:

Plum Eyewash 0.9% Sodium Chloride is to be used as a first aid product for eye irrigation.

We guarantee and declare that:

1. The device is a Class Is device according to Annex IX, rule 5.
2. The irrigation fluid is STERILE
3. The planning and manufacture procedures are conducted in conformity with the Company Quality System, in compliance with the provisions of Annex VII combined with Annex V to the Directive.

The notified body DNV Product Assurance AS (ID No.2460) certifies Plum Safety ApS.
The latest EC Certificate No. 10000457813-PA-NA-DNK 2021-05-05.

Assens, 2021-05-06

Regulatory Affairs and Quality Assurance Manager

Mandelalléen 1 • 5610 Assens Denmark • Tel. +45 6916 9600 • info@plum.eu • www.plum.eu

CE DECLARATION OF CONFORMITY

Plum Eyewash pH Neutral 4.9% Phosphate

Eye irrigation fluid for first aid

We, the manufacturer, of the products covered by this declaration, hereby declare, that the bottles with sterile irrigation fluid listed below, meet the requirements in the Council Directive 93/42/EEC of 14 June 1993, the Directive 2007/47 /EC and its relevant transposition into national laws of the member states into which we place the device. Plum Safety ApS is responsible for the Declaration of Conformity concerning the medical devices listed below:

Art No	Art Name	Volume
4752	Plum Eyewash pH Neutral 4.9% Phosphate	200ml
4747	Plum Eyewash pH Neutral 4.9% Phosphate	500ml
4746	Plum Eyewash pH Neutral 4.9% Phosphate Shower	1000 ml
4801	Plum Eyewash pH Neutral 4.9% Phosphate DUO	500ml

With the intended purpose:

Plum Eyewash pH Neutral 4.9% Phosphate is to be used as a first aid product for eye irrigation involving accidents with acids and alkali.

We guarantee and declare that:

1. The device is a Class Is device according to Annex IX, rule 5.
2. The irrigation fluid is STERILE
3. The planning and manufacture procedures are conducted in conformity with the Company Quality System, in compliance with the provisions of Annex VII combined with Annex V to the Directive.

The notified body DNV Product Assurance AS (ID No. 2460) certifies Plum Safety ApS.
The latest EC Certificate No. 10000457813-PA-NA-DNK 2021-05-05.

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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 QuickFix plasters

Reference number:

Art No	Art Name
5511	Plum QuickFix Water resistant
5512	Plum QuickFix Elastic
5508	Plum QuickFix Elastic Long
5504	Plum QuickFix Elastic Mini
5518	Plum QuickFix Elastic Micro
5513	Plum QuickFix Detectable
5509	Plum QuickFix Detectable long
5515	Plum QuickFix Alu
5519	Plum QuickFix Alu Micro

Intended purpose:	Plum QuickFix plasters are used as a first aid product as mechanical barrier and for absorption of exudates.
Basic UDI-DI:	5715205QFPLASTER01SS
Device classification:	Class I, according to Annex VIII, Rule 4

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. This declaration is supported by the Quality System approval to ISO 13485 issued by Presafe Denmark A/S, Certificate No.: DGM-940.

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:
Assens, 2023-03-28

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Katarzyna Luiza Grzych
Person Responsible for Regulatory Compliance