

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 the 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, Mono	200ml
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.

Assens, 2025-01-28



Regulatory Affairs and Quality Assurance Manager






Plum Safety DoC 2025- Plum Eyewash pH Neutral 4.9 Phosphate

Final Audit Report

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